

To:

June 14, 2006

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

Respected Sir

Sub: Bt BRINJAL – HUMAN HEALTH HAZARDS AND BEYOND

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

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

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

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

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

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

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

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

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

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

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

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

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

2. The other genes introduced are toxic too:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. Potential environmental hazards with Bt Brinjal:

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

India is a Center of Origin and diversity for Brinjal: Our pool of genetic reserves would inevitably be contaminated and this is extremely dangerous given that we are a Centre of Origin and diversity for Brinjal. We have grown Brinjal for the past 4000 years in this country and it is an extremely popular and widely consumed vegetable. Needless to say, horizontal gene transfer from Bt Brinjal into wild, related species of brinjal has serious implications for the very future of Brinjal research and cultivation in the country. The genetic diversity is important because some of the strains will be naturally resistant to lethal pathogens and pests that may destroy the crops in the future. Once lost, this lack of diversity can lead to the complete loss of the crop. Several published experiments with Bt in rapeseed and sunflower have provided preliminary data that Bt genes can indeed give some wild plants a competitive advantage. If the gene spreads in wild relatives of brinjal, its escape into the environment will be permanent. The toxin produced by the gene may then kill insects that feed on the wild plants. India is a haven of butterflies and the Cry1 Ac gene targets lepidopterans including these

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

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

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

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

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

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

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

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

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

afford to make similar mistakes again?

Given all the above, we demand that:

Since the effects of this technology/modified organism are unknown and since these are potentially hazardous, the use of this technology and release of those organisms must wait until the hazards are properly understood and the effects known. **This requires the precautionary approach to be followed.**

Biosafety testing should include testing for medium and long term effects on the environment and human/animal health, in addition to asking questions on the justification of releasing the GMO into the open environment on social and ethical grounds. For this, the regulators as a beginning, should put together all the available data on safer alternatives, as any environment assessment should, like IPM, NPM, organic etc., and compare Bt Brinjal with such alternatives.

Proper biosafety tests should be taken up by **independent and scientifically competent bodies in a transparent manner**. Such tests should be allowed to take appropriate time needed to understand the medium and long term effects instead of being hastened in the pursuit of 'fast-track approvals'.

The results of such tests **should be made public** and data published in a manner that it can be closely examined by the scientific community. It shall also be **presented to all primary stakeholders [farmers and consumers]** in a manner that meaningful debates are possible, through for instance, mandatory public notice and public hearings etc.

Such reviews and debates should also look at issues beyond biosafety and delve into socio-cultural and political aspects related to GM agriculture, given that millions of our lives and livelihoods depend on agriculture here in India.

The GEAC, especially representatives from the Health Ministry, Environment Ministry and the Agriculture Ministry on the Committee, should take on board current scientific data [health and environmental] from elsewhere to understand the potential impact of GMOs and to ask the relevant questions in the Indian context. Based on such available data, they should lucidly justify why a precautionary principle cannot be invoked straightaway, instead of falling into the trap of the Department of Biotechnology which apparently has only one mandate of promoting GMOs.

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

Sincerely,

Sd/- Members of Coalition for GM-Free India

Annexure 9:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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