

Advancing the Understanding of Biosafety

Latest scientific findings, policy responses and public participation

Lecture

India's Bt Brinjal: From the Supreme Court to Science in Public Debate

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Session

Key Note Lectures

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The picture is incomplete. We must still win the war of obtaining a moratorium on GM crops, because they present bio-safety hazards which have not been disproved by the Indian Regulators and the 'Industry' in stringent and independent safety testing protocols. The approval of Bt brinjal for commercialisation by the apex Regulator the GEAC (the Genetic Engineering Approval Committee), had it not been stopped by Jairam Ramesh, India's Minister of Environment & Forests, then that would have been 'open sesame' for Monsanto and the biotech industry all the way to the last Indian food crop. That was the plan. It is still the plan.

The battle of Bt brinjal is an extraordinary one by any standard. I am told for example, that it is a first of its kind. I would agree with that for two reasons of my own. The first is not apparent except within India. The response to the idea of a genetically engineered national vegetable, the most important vegetable in India (the potato is not a vegetable) raised a national storm in a rare demonstration of co-operation nationwide, not seen since India's independence in 1947. Ramesh also embarked on perhaps, the first democratic consultative process with civil society in India (in the spirit and letter of the CPB), in 7 well-managed and fully documented public consultations conducted in carefully selected, important Indian cities, (Annexures I-IV <http://www.moef.nic.in>). I can assure you that this was courageous! He was swamped, (more on these aspects later). The second is also relatively unknown except to an insider like me of this particular story. Bt brinjal is perhaps a unique first also because it properly belongs to the arena of international co-operation. The super stars in the galaxy of stars in this fantastic saga that is stranger than fiction are a special breed of human beings who are also eminent international scientists and acknowledged experts in their particular specialism. They rolled up their sleeves, put aside large chunks of time, burnt the mid-night oil to keep time- lines demanded by court schedules and plunged into the very hard work, made harder still for having to provide and explain scientific evidence to a NON-SCIENTIST! That process began six years ago. The core group of 4, which later doubled and even trebled as others joined the battle over the ensuing years (and on-going), to provide evidence that has filled numerous volumes are: Dr Arpad Pusztai, Prof Jack Heinemann, Prof David Schubert and Dr. Doug Gurian-Sherman. But my particular thanks are reserved for Providence who sees fit not to usually disclose the future. In my case, with the greatest good will of even these great examples of kindness, had they known what was in store for them, they would have rightly avoided me. I recall the first affidavit I received from David Schubert. I looked at it, completely baffled and in alarm. I didn't understand a word. Finally, I put aside every shred of self respect and said to David: "*I comprehend the verbs that join the nouns. That is all. Please would you rewrite this in plain English*". He did. After that, it went pretty smoothly.

GM crops make for dull news. Prior to the Bt brinjal debacle, there was near complete ignorance about these crops. There was certainly disinterest. But Monsanto with its deep pockets, regularly beat their drum on mythical, miracle yields of GM crops, the 'success' of Bt cotton (the only commercialised crop in India) and the easy unscientific claim that GM crops would feed the world. Yet, the battle of Bt brinjal had to be fought in the public domain if we were to succeed. The evidence in the Supreme Court had to somehow be catapulted on to the outside, broadcast and understood. Thus far, we had failed miserably. And then something happened to catalyse the required widespread agitation by Civil Society across India on an unexpected scale. I call it the 'Rub of the Green'. I'm in Japan, a golfing country so this is a phrase I am sure that is widely understood. Like a green genie of the environment, Jairam Ramesh was the right MAN, in the right place at the right time, driving the unique Bt brinjal orchestra of science, civil society and public debate, in an extraordinary story that has all the magic and exhilaration of deflecting a golf ball into the right lie for an eagle. The coincidence of that time and place were made possible, in my opinion by events in the form of

ORDERS of the Supreme Court and a timely General Election! What follows is the perspective from where I stand and have stood for 5½ years on the steps of the Supreme Court of India, with Prashant Bhushan (the able advocate on this case), and onward into Court No 1, where the Chief Justice of India presides with his Brother Justices to hear among other cases, the **Public Interest Writ Petition (PIL)** for a moratorium on GM crops. The writ petition has had its ups and its downs and no doubt, this will continue, but the ups were pivotal. They represent the milestones and the watershed that made for a coalescing over time, of a situation where science in the cloistered hall of the Supreme Court (SC) found its way into the public arena and an agitating civil society that took up that science, and a media that was now agog, because of that *rub of the green*. These are the highlights of that process.

The PIL and its 'Grounds'

The 'Grounds' of the Supreme Court (SC) writ petition are: (a) the scientifically unsound release of GMOs were in violation of the Directive Principles of the Constitution of India, specifically Article 21 whereby the right to health and a safe environment are a fundamental right; (b) the Cartagena Protocol the binding International protocol on biodiversity to which India is a signatory; (c) the Precautionary Principle, (also of the CPB), which has also been upheld in Indian law and is a precedent:

Orders of the SC: Milestones and a Watershed

Acting on an 'Urgent Application' filed in July'06, the Chief Justice 'Ordered' *an interim ban on all field trials in September '06*. The timing was crucial as it scuttled the approval of the Bt brinjal large scale field trials and set back the regulators' plans and Monsanto by at least one planting season or **near 12 months**.

The Watershed Order

In February 2007, we succeeded in obtaining an Order for the bio-safety raw data of Bt brinjal to be put on the Ministry's website (in the public domain). Even so it took 18 months for India's apex Regulator, the GEAC to comply, which was in August 2008. In hindsight, even this was a good thing! *Here was the watershed*. I sent out an SOS. Four scientists responded and sent in their critiques as evidence to the SC: (a) The critical evaluation of the animal feeding studies by Gilles-Eric Seralini; (b) Molecular characterisation and Genomics by Jack Heinemann; (c) Gene Flow to wild brinjal relatives by Doug Gurian Sherman; (d) Sampling and statistical significance of the data of animal feeding studies by Judy Carman.

The immediate impact of these appraisals was to force the GEAC to appoint an expert committee to evaluate them, called the Bt brinjal Expert Committee II (EC II) which was convened in early 2009.

What Followed

Following a General Election in May 2009 which re-elected Manmohan Singh as Prime Minister, Jairam Ramesh was appointed Minister of Environment & Forests. His appointment was to be pivotal. When on the 14th October 2009, the GEAC accepted the ECII report recommendation to commercialise Bt brinjal, he stepped in the next day to bar it in a pro temp measure of review because of the nationwide criticism of the EC II Report.

He had been in office just 4 1/2 months!

During October '09 to end January 2010, Ramesh instituted a process by which he invited documented responses to the EC II Report from all stake holders including the international community of scientists. Ramesh's initiative was uniquely democratic. He received in excess of 2 dozen scientific appraisals. This was astonishing and reflects the importance of the implications of releasing the world's first major GM food crop, the brinjal, in the world's centre of diversity and origin.

The impact of the Jairam process galvanised the media. It exploded. By February 2010, India and the world had heard of Bt brinjal. The scientific data from the SC started to percolate

through to our State Agricultural Ministers, NGOs, and farmer organisations. When the Public Consultations were held between January and the 6th February 2010, civil society, farmers, and State Governments were primed and ready. In a first of their kind, fully documented and video-taped, the 7 Consultations proceeded with virtual pomp and ceremony uniquely Indian, the din and dust, colour and theatre and eventually order! **631 comments** from stake holders were recorded that reflected a surprising level of knowledge of the science and implications of Bt brinjal and a perspicacity. Glued eyeballs to TV screens followed the fascinating consultations and debate. Civil Society did an outstanding job of management and dissemination; and Science had trickled down to our NGOs and right into our farming households. 10 State Governments, which include the major brinjal production centres in Eastern India, said “no” to Bt brinjal. Agriculture in India’s federal system of government is a State subject. We have 28 States.

On the 9th February 2010, Jairam Ramesh announced a moratorium on the commercial approval of Bt brinjal, citing the need for further safety testing, and declared that that he had been “*responsive to society and responsible to science*”. This was an extraordinary conclusion brought about in an unlikely series of events that converged and coincided to topple Bt brinjal and stop its approval for commercial release: the Rub of the Green that brought India back from the brink.

One hour before his announcement, Nina Federoff (US Science and Technology adviser) who flew into India to reportedly demonstrate US support for transgenic brinjal, had special advice for the Indian Government when she declared on TV that Bt brinjal is good for India.

The Risk Assessment of the Bt Brinjal EC II Report & Gaps

Bt brinjal Event EE1 encodes for a chimeric (Cry1 Ac and Cry1 Ab) or fusion gene to be composed of three transgenes:

- *cry1Ac*, the gene for the insecticidal protein (coupled with the heterologous promoter called 35S from the cauliflower mosaic virus);
- *nptII*, a gene that confers antibiotic resistance; and
- *aad*, another gene for antibiotic resistance

The Risk Assessment by the Government was found deficient on the following grounds:

Health: Bt Brinjal, has been modified to produce an “*unknown*” chimeric insecticide toxin containing “**Cry1Ab and Cry1Ac modified sequence**”. Bt brinjal has 16-17 mg insecticide toxin per kg, as compared to Bt maize (1 mg/kg), (Seralini)”. The cry gene used was in fact a chimeric arising out of the laboratory and not the soil. The case for the safety of Bt brinjal was heavily based on the GEAC supposition that Cry proteins had a history of safe use. However, as noted in submissions to the GEAC by independent scientists, this supposition lacks merit. The various Cry proteins do not have a history of safe use in the diet of mammals and there is an absence of literature to support any claim to the contrary. There were indications of a possible toxic effect to livers and kidneys from the GM plant that were revealed by a careful reading of the evidence in the dossier. (Response to EC II health impacts, Seralini).

A Single Rat-Feeding Study of 10 Rats is Used to Support Mahyco’s Application for Safety for 1.15 billion Indians (10 rats each, male & female): This small sample size is central to the “*inadequacy of the study’s statistical power to find anything adverse*”. Again, 90 days is woefully inadequate to determine long-term chronic health effects which include tumours and cancers and of 1.15 billion Indians eating GM brinjal for generations. (Monsanto’s Dossier, rat feeding studies, statistical analyses: **Judy Carman**).

BOTH EXPERTS CONCLUDE THAT THE RELEASE OF BT BRINJAL MUST BE FORBIDDEN BECAUSE OF POTENTIAL SERIOUS RISKS TO HUMAN AND ANIMAL HEALTH

Genomic Analyses: A proper safety assessment includes a molecular (genomic) level profile of the modified plant. A critical first step in a comparative process of risk assessment is hazard identification. This begins with an evaluation of the GM plant and is assisted by full and accurate

descriptions of both intended and unintended changes that arise from the modification or the process of making and isolating the modified plant. The GEAC cannot conclude from Mahyco's data that there is a single insert and no additional inserts of unexpected size or sequence composition. The Bt brinjal producer has not submitted, and GEAC has not claimed to have reviewed or considered such approaches and data. Hence a thorough and meaningful hazard identification has not been possible. (Response to EC II Genomic Analyses: **Jack Heinemann**).

Gene Flow: Mahyco presents no data that assesses the risks of gene flow from Bt brinjal to wild relatives. The company presents data that is wholly inadequate to predict gene flow. Several wild relatives of brinjal are found in India and have been shown to be sexually compatible with brinjal. Further, methods to prevent gene flow from crops to wild relatives currently do not exist. Gene flow from Bt brinjal to wild relatives, if commercialised, would therefore be virtually certain. (Response to EC II: Gene Flow **Doug Gurian Sherman**)

Environmental Risk Assessment: Brinjal plays a unique role in Indian society. It is one of the most important vegetable crops in India, especially for the rural and urban poor. About 61% is grown in the three eastern states of West Bengal, Orissa and Bihar by **small-scale resource-poor farmers**. These States have banned the use of Bt brinjal. India is the **centre of the world's biological diversity in brinjal** with over **2500 varieties** grown in the country. Some local varieties have significant religious and cultural value.

Event EE-1 Bt brinjal poses several unique challenges because the likelihood of resistance evolving quickly is high. Without any management of resistance evolution, Bt brinjal is projected to fail in 4-12 years. Farmers are expected to retain only 10% of the increase in profitability from Bt brinjal, but are expected to retain 63% of the increase from brinjal IPM (Integrated Pest Management).

EC-II does not acknowledge this risk and the Dossier does not propose effective means to manage it. The evolution of resistance to Bt crops is a real risk and is treated as such throughout the world. ('The scope and adequacy of the GEAC environmental risk assessment'; **David Andow**)

International Protocols: Despite the GEAC claim, the EC-II report does not meet India's international obligations under all relevant treaties. There are 2: (a) India is bound by the provision of the Cartagena Protocol of the CBD The Protocol under A.2(2) stipulate parties to ensure that the development, handling, transport, use, transfer and release of any living modified organisms (LMO) are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account the risks to human health and socio-economic and ethical implication in the spirit of Articles 15 and 26 of the Cartagena Protocol on Biosafety; (b) Codex Alimentarius Commission (CAC): *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and its supporting document the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2003, CAC/GL 45-2003)* for its assessment of potential effects to human health. The lack of compliance of the EC-II Report to both the Cartagena Protocol and Codex highlights a serious deficiency in the EC-II assessment.

Animal feeding Studies for Chronic Toxicity: The regulator didn't require anything more than the sub-chronic 90day rat feeding study, yet, long term, multigenerational and life time animal feeding studies are required to reveal long term effects like cancers and reproductive problems.

Allergenicity: testing was not Codex compliant.