Response on GEAC approval for Commercializing Bt Brinjal

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Introduction: New Technologies often have great potential and promise much, but also need to be assessed adequately in order to establish the relevance and ensure that they are safe, as well as environmentally and socially sustainable. Genetic Engineering and Genetically modified crops are examples where, despite promises and expectations of benefits, concerns remain over their potential risks to human health and environment. Moreover there are many socio-economic considerations that need to be taken into account, particularly in a country like India where small farmers and small farms are in majority and where the farmers are already in ecological and economic distress. Therefore before taking any decision on such critical issue decision should be based on assessing

1. **Environmental Risk Assessment:** The process of Genetic transformation is imprecise hence needs a relevant risk assessment frame work based on the ecological and socio-economic conditions of adoption.
2. **Relevance of technology:** India being a country of small farmers and small farms, the relevance of the technology should be assessed in the conditions and against the available best technologies.
3. **Transparent and Accountable Regulatory system:** The processes adopted by the regulatory system should transparent and be accountable for the decisions being taken in assessing the potential risks.
4. **Socio-Economic Impact:** The socio-economic impact of any technology should be assessed in specific context. This impact assessment should also include the impacts of seed prices and the IPRs involved.

Bt brinjal: Bt Brinjal is a transgenic brinjal created out of inserting a gene [Cry1Ac] from the soil bacterium *Bacillus thuringiensis* into Brinjal. The insertion of the gene into the Brinjal cell in young cotyledons has been done through an *Agrobacterium*-mediated vector, along with other genes like promoters, markers etc. This is said to give the Brinjal plant resistance against lepidopteran insects like the Brinjal Fruit and Shoot Borer (*Leucinodes orbonalis*) and Fruit Borer (*Helicoverpa armigera*). It is reported that upon ingestion of the Bt toxin by the insect, there would be disruption of digestive processes, ultimately resulting in the death of the insect.

The Framework for Risk Assessment

The integration of foreign DNA into an established genome may have unanticipated side effects, e.g. chromatin changes, genome instability, unexpected protein products

from transgene(s), and influence on overall organismal gene expression patterns in quantitative as well as qualitative terms, of the recipient organism. Therefore there is a general need for a holistic and integrated basis for assessment of the properties and effects of GMOs (Haslberger, 2006). This conclusion was also drawn by a recent World Health Organisation (WHO) report (2005).

Therefore the Environmental Risk Assessment of any GMO particularly as food is critical before releasing into the environment. In this context before deciding on the Bt Brinjal we need to review the experiences of last seven years of Bt cotton. While the governments and industries makes big claims of production improvement and India raising to second position in terms of production in the world. But the reports of Planning commission on Vidharba (Planning Commission, 2005) Animal Deaths from Andhra Pradesh (Animal husbandry Department, Govt of AP, 2007), Skin allergins from Madhya Pradesh (JSA, 2005) have brought in ecological risks associated with the this so called big 'Cotton Revolution'. Though many promises were made on reviewing the Bt cotton performance, neither Ministry of Agriculture or Ministry of Environment of Government of India have made any beginning on this. And today, the risks posed to the people in terms of health, livelihoods, and resources are not considered in assessing Bt Brinjal.

1) **Toxic effects on non-target organisms** (including food chain and soil organisms): Reports on mortality of sheep and other small ruminants after grazing on Bt cotton plants from Andhra Pradesh, Maharashtra and other parts of the country. Animal Husbandry department of Andhra Pradesh have clearly raised doubts over the biosafety tests done and impacts of bt cotton.

What EC-I recommended (B. in page 3 of EC-II report)	**What EC-II said**	**Comments**
g. Soil impact assessment study should include tests on the total microbial counts related to Rhizosphere on the soil of Bt and normal	• Soil impact assessment study was conducted on soil samples collected from Bt brinjal large-scale trial conducted at Parbhani (Maharashtra) during 2007-08 and 2008-09 as per protocol approved by IIVR . • The study included tests on the total microbial counts related to rhizosphere.	• EC-I recommended to record the **impacts on the second crop and this was not done.** • **Root exudates and enzymatic activity were not studied.** • The reports suggest that there is no Bt toxin identified in the soil where as many earlier studies including on Bt cotton in India by IARI and in a study by

	The counts included bacterial population, fungal population, earthw orm and Collembola. The samples were drawn prior to sowing as well as post harvest up to 180 days after transplanting. • No Cry1Ac protein was detected in any of the soil samples. • The Cry1Ac protein was estimated in the samples grown from both root and non root zones at different depths i.e. 30 cm, 60 cm and 1 metre.	Australian university Bt toxins were found in the soils for significant time (more than 45 days). In the case of Bt Brinjal if the reports are saying no Bt toxin was detected, the methodologies need to be rechecked. • Data shows variations between microbial profiles between soils growing Bt brinjal and non-brinjal but no statistical analysis was done to say whether it is significant. • At 30 DAT sampling point the **collembolla population was a little more, & at 60 DAT sampling point it was quite low as compared to the other time points,** and argues that it is an isolated instance.
i. The Food / Feed Safety assessment should include foliage toxicity study in Goats'	GEAC decided to dispense with this requirement on the following grounds: i. The reports of sheep deaths due to Bt cotton were unsubstantiated. ii. RCGM indicated that large mammals like goats are not used for toxicity studies using whole foods, anywhere in the world and there are no scientific references on validation of goat as a	• The postmortem reports showed that there were no known toxins (including pesticide residues) and known diseases in the caresses. The analysis showed that bt cotton plant leaves had higher nitrate content which is unusual compared to non-bt cotton leaves. The recommendation was based on the reports of sheep deaths

	model for studying sub-chronic feeding studies. iii. Brinjal leaves are not part of natural diet of goats and thus feeding protocol cannot be scientifically validated.	in AP after feeding on bt cotton and AP Director AH writing to GEAC on this. Open grazing in farms is a real situation in India. The GEAC lied on various occassions on this issue to the nation saying IVRI has studied where as IVRI neither visited the sites nor done any studies. International Codex is only minimal set of guidelines to be followed. We need to design additional biosafety tests based on real situations.

2) **Allerginicity:** Bt Toxin is known to have many allergic and toxic properties (Swadener, 1994). Even in India, several complaints were made by the farmers and agriculture workers in AP and other parts of the country. In Madhya Pradesh Skin, Upper respiratory tract and eye allergies were reported by persons exposed to cotton. The symptoms vary from mild, moderate to very severe to the extent that one women had to be admitted for 9 days as a result of allergy. The allergy is not restricted to farm labourers involved in picking cotton but has affected labour involved in loading and unloading Bt from villages to market, those involved in its weighment, labourers working in ginning factories, people who carried out other operations in the field of BT cotton, or farmers who stored cotton in their homes etc. Thus the symptom is affecting people widely exposed at different places. The symptoms were not restricted to one particular farm but several farms in 6 villages spread around 4 tehsils of 2 districts. (Jana Swasth Abhayan, 2005).

EC-I recommendations	EC-II report	Comments
h. Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits shall be undertaken at Central Food Technology Research	• CFTRI, Mysore was approached for flavour study. However, they expressed their	The decision on a Food crop cannot be taken without doing safety assessment. The new guidelines are result of

Institute (CFTRI), Mysore/ any other NABL accredited Laboratory.	inability to conduct study on transgenic crop product at this stage. • There is a deviation as the **institution refused to conduct the study**. However, as per the recently adopted "Guidelines for safety assessments of food derived from GE plants, 2008", such kind of studies do not form part of safety assessment. EC-II is of the view that such studies are not required as per the internationally prescribed Codex guidelines and national guidelines prescribed by the GEAC. Therefore, studies of such nature need not be a prerequisite for consideration for environmental release.	the USAID initiative in the name of harmonizing IPR systems and two of the members of the expert committee were part of that exercise. A clear conflict of interest
j. The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines shall be conducted.	RCGM was of the view that such skin sensitized tests on plants has **no relevance** especially when Bt brinjal has found to be safe in the feeding studies and even the purified Bt gene has been extensively studied for toxicity and allergenicity. The guidelines since have been revised and the **study is not required** as	Skin allergies were reported by agriculture workers and farmers while working in the bt cotton fields. Expert committee only talked about the allerginicity of the bt toxin consumed as part of the food. There are enough evidences to show that pure bt protien has allergic/toxic properties on humans and

	per the "Guidelines for safety assessment of foods derived from GE plants, 2008"	animals (Swadener, 1994)
k. Additional toxicity/ allergenicity/compositional/ nutritional studies, if any, as recommended by Director, National Institute of Nutrition (NIN), Hyderabad shall be conducted.	• Raw data has been examined by Director, NIN and found to be satisfactory. • No additional studies were recommended by Director, NIN regarding toxicity and allergenicity except the need for detailed compositional analysis. The same has been initiated by the applicant after the protocols was approved by RCGM in its 77th meeting held 02.05.2009.	The information from NIN under RTI shows that NIN director only looked at **data from 3 tests** and on what basis NIN Director expressed his satisfaction over the entire data sets? Earlier, he also raised questions regarding the genuinity of the samples supplied. This was not answered.

3) **Effects on Biodiversity:** One of the major concerns of release of GM crops into environment is the problem of impacts on the Biodiversity in terms of genetic contamination of other non-gm varieties and wild relatives, pest shifts, in addition to aggressiveness and weediness. The Mexican experience shows that the maize germplasm collection in even in CIMMYT. The introduction of Bt cotton in India has has not only seen displacement of non bt cotton varieties/hybrids but also contamination of the non bt cotton varieties/hybrids due to outcrossing and seed mixtures. This has led to rejection of organic cotton exports from India. In addition, the sucking pests like mealy bug, whitefly and jassids have increased which resulted in similar use of chemical pesticides. The increase in sucking pests which acts as vectors have increased the incidence of viral diseases.

   In Bt brinjal field trials also such problems were observed but not taken serious. The incidence of new diseases particularly virus transmitted little leaf etc have to studied before taking any decision.

   Disowning the Centre of Origin: While across the world, efforts are being made to own and protect the biological resources, the Bt brinjal has started a dangerous trend of disowning the claim of India as the Centre for Origin of Brinjal. The

Mahyco's own first report shows that India is the centre of origin, while the later reports deny the fact. Leaving aside the debate on centre of origin one has to accept that India as one of the major Centres of Diversity. This is a criminal offence and National Biodiversity Board should initiate legal action on all the concerned.

Relavance

Before introduction of any new technology one need to see and the need of the technology in the ecological and socio-economic situation into which the technology is introduced. In India, Brinjal is grown in about 5.5 lakh acres of which majority (more than 85 %) is grown in less than half acre that too in a mixed/intercrop situation. There was never a short fall in production. The high use of pesticide in brinjal for managing brinjal fruit and shoot borer is seen but it is mostly in the monocropped and high chemical used conditions. There are safer practices as Integrated Pest Management (Alam, 2003, Srinivasan, 2008), and Non Pesticidal Management (which can be used for effective management of Brinjal fruit and shoot borer.

Efficacy compared to best management practices: The field trials should focus on establishing the efficacy of Bt Brinjal in managing Brinjal Fruit Shoot Borer. Neither in the Multilocation field trials nor in Large Scale Field trials, the Bt brinjal was tested against the Best available management practices like IPM and NPM. The Large scale field trails also have not included the local check. Asian Vegetable Research and Development Centre, Bangkok and Natural Resources Institute, UK have established the IPM and NPM practices widely in India in partnership with Tamil Nadu Agriculture University, Gujarat Agriculture University and Centre for Sustainable Agriculture (Centre for World Solidarity earlier) during 2000-2003. The practice of NPM on large scale covering more than 14 lakh acres during 2009-10 in Andhra Pradesh in various crops clearly shows that Eco-Friendly practices like NPM are effective and possible to adopt on large scale (World Bank, 2009).

Abiotic Stressess: In a situation where in increasing costs of cultivation are impacting farmers, and much of the crop is grown in small plots and in rainfed conditions, introduction of GM crops proves detrimental. The report of Planning Commision on Vidharba farmers Suicides clearly shows that the Bt Cotton was highly susceptible to drought situations. The field trails have ignored this issue.

Being a native crop to India, rich diversity exists in Brinjals. Brinjal has many medicinal uses and used extensively in traditional medicine like Ayurveda

and Sidda. Any genetic contamination of the existing traditional varieties like udipigulla, mattugulla etc will threaten their medicinal usage forever.

IPRs on Bt Brinjal, farmers' rights and Seed prices: the Bt Cotton seed prices has forced several state governments like Andhra Pradesh and Gujarat to move to court and initiate new legislations to regulate the seed prices. Even without any legally protected rights in the case of Bt Cotton, state governments and farmers and even Indian seed companies had to contend with the monopolistic behaviour of Mahyco Monsanto Biotech, the issues are going to get murkier with Mahyco owning a Bt Brinjal and technology being licensed from Monsanto. having a patent over technology. Further, public sector universities have parted with their germplasm, with the initial varieties obviously belonging to some farming community or the other, to develop Bt Brinjal varieties in a consortium project called ABSPII. In all of this, it is not clear who has the authority to regulate seed sales, pricing and royalty issues, who is claiming ownership and how on the germplasm that belongs to farmers that the public sector then developed into Bt Brinjal varieties and it is not clear who owns the Bt Brinjal varieties!!

Does Large scale adoption means farmers accepted the technology: Adoption of a technology doesn't mean it is safe and desirable. In India 85 % farmers growing cotton have shifted to Bt cotton, this doesn't mean that it is safe are farmers are happy. Adoption of varieties/hybrids is based on the existing choices to the farmers. The situation is mainly because of

a) Absence of good quality non bt cotton seed being not available to farmers as Agriculture Universities and State Seed Development Corporation have not produced any cotton seed in the last three years.
b) From 2003 on wards the public sector majority of the public sector varieties and hybrids were systematically denotified and withdrawn from commercial cultivation. No new varieties/hybrids were released during the period.
c) Farmers' choices largely being influenced more by market than performance and self understanding. Closer analysis of the dynamics of adoption shows that the pattern some see as an environmentally based change in agricultural practice actually continues the established pattern of socially driven fads arising in the virtual absence of environmental learning.

Who regulates the Regulation? The scandals seen from the day illegal field trials of food crops like Bt brinjal, Bt Okra and Bt Rice were unearthed in a remote villages of Andhra Pradesh by Centre for Sustainable which have violated all stipulated conditions to the date where the Expert Committee Chairperson claims that he is under tremendous pressure to approve Bt Brinjal shows industry regulating the regulatory process rather being otherway round. The Chairperson of the EC-II, Dr. Arjula Reddy made a honest confession that he only looked into compliance to rules

rather than biosafety as per the changed guidelines and he is not sure of the biosafety of the Bt Brinjal.

Who changed the regulations? Among the biosafety tests to assess the Environmental Risk prescribed by EC-I the company has not the done the critical ones like Foliage toxicity study as part of the Food/Feed safety assessment, Skin allergy Testing, flavor analysis, skin sensitization test. EC-II claims that these tests were not done because

- RCGM has suggested not to do, or
- Not prescribed by the new 'Guidelines for safety assessment of foods derived from GE plants, 2008'.

Interestingly, it was some of the members of the regulators who recommended change of the USAID project. The honesty of the RCGM secretary stands questioned as complaints were found lodged against him by the GM seed companies in Banjara hills police station, Hyderabad for demanding bribes and an enquiry from Central Vigilence Committee is still pending.

The recommendations made by Eminent Scientist like Dr. Pushpa Mitra Bhargava as Supreme Court Observer to GEAC for further tests were ignored.

Given this situation we strongly urge Hon'ble Minister for Environment

- **to withdraw the Expert Committee-II report first**
- **reconstitute GEAC giving legal space to independent members**
- **define the frame work and tests for Environmental Risk Assessment and establishing relevance compared with best practices and specific to brinjal growing ecological and socio-economic conditions**

References

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About us: Centre for Sustainable Agriculture is an Independent Agriculture Research Organization engaged in establishing Sustainable Agriculture Models in Andhra Pradesh, Punjab, Maharashtra and Chattisgarh. CSA has a long and successful history of working on Non Pesticidal Management in agriculture on a large scale (7 lakh acres in Andhra Pradesh on several crops including cotton and brinjal without using pesticides and GMOs). As an organization working with lakhs of small and marginal farmers in AP and other states have concerns about technologies being thrust on farmers without adequate Environmental Risk Assessment and Socio-Economic impact assessments.

Jatan Trust is an organization working in promotion of organic farming in Gujarat.

Thanal is an organization working on promoting organic farming, zero waste management in kerala

Sahaja Samrudda is a group working with organic farmers in Karnataka.

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