# IS BT BRINJAL SAFE? IS IT NEEDED? Independent analyses of Bt Brinjal biosafety assessment data

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# Worldwide,

- A vast majority of the countries do not grow any GM crops in the first instance!
- USA still is the one country with the largest GM area in the world - America is desperately looking for markets for such biotech products – seed markets as well as food markets….
- Bt Brinjal was developed in India by American agencies (Monsanto's Indian partner Mahyco, USAID, Cornell etc.)
- While Philippines rejected Bt brinjal after India, Bangladesh allowed it for cultivation in 2013-14, with USAID support
- Bangladesh is reporting crop losses, seed stocks lying with government, and only 3% Bt brinjal adoption by area, that too with incentives from govt….

# Bt Brinjal development in India

- Plasmid obtained and imported from Monsanto in 2000 (pMON10518 containing '*cry1Ac*' gene) by Mahyco
- Biosafety evaluation from 2002 onwards!
- Open air trials in farmers' fields from 2004 – violations in FTs recorded quite early on…No liability fixed by regulators however…
- 2004-05 – Included in AICRIP-Vegetables by ICAR
- 2004 – ABSP II project for Bt Brinjal (varieties) development in a consortium project involving TNAU, UAS-D and IIVR begins

# Bt Brinjal progresses further….

- 2006 – Large scale trials application put in – huge resistance from across the country – “LSTs without biosafety being cleared?”
- EC1 (Expert Committee 1) constituted by GEAC (12 members – one didn’t participate) – Chair is a GM crop developer; 2 were GM technology providers and 1 involved in ABSPII; 1 from DBT is accused of excessively favoring Mahyco and had a CVC complaint pending…
- EC1 recommends “independent assessment by IIVR” – how is this possible when IIVR is part of ABSPII developing Bt Brinjal?

# Bt Brinjal's inexorable progress…

- Mahyco applies for one season's large scale trials and gets two years' permission from GEAC in 2007!
- EC1 report put in the public domain after the decision was taken to allow Large Scale Trials without biosafety being cleared….violation of existing norms
- Biosafety data denied despite CIC's orders
- SC orders biosafety data to be put out in the public domain in mid-2008
- Data put out in August 2008
- Independent scientific analyses starts coming in from January 2009, for the first time…

# Bt Brinjal's regulatory evaluation and its last stages....

- The mandate of an Expert Committee gets changed inexplicably (next slide)
- The constitution, ToR and processes could have had only one outcome: approval!
- October 8th 2009: EC2 report finalised, after 2 sittings
- October 14th: GEAC clears Bt Brinjal, based on the EC2 recommendation
- October 15th: MOSEF announces nation-wide consultations before GoI takes a decision; calls for feedback on EC2 report
- November 17th 2009: Reports of several studies put out in the public domain for the first time!

# EC2 mandate: GEAC 91st meeting minutes (January 14th 2009)

"5.1.4 After detailed deliberations, the Committee decided to set up a Sub-committee comprising of representatives from the Ministry of Health and Family Welfare, NIN, ICMR, CFTRI, CCMB, IIVR, NDRI, CFIE, MoEF, DBT, TNAU and UAS Dharwad with the following terms of reference:

- to review the adequacy of the biosafety data on Bt brinjal
- to review the adequacy of the toxicity and allergenicity protocols
- to suggest further studies, if any, based on the review of the international practices in biosafety
- assessment and representations received by the GEAC
- based on such reviews make suitable recommendations for consideration of the GEAC".

# EC2 Actual Terms of Reference

Created on 29/5/2009 through an Office Memorandum by GEAC:

- to review the findings of the data generated during the large scale trials ;
- to review the biosafety data of Bt brinjal in light of the available scientific evidence, reports from international/national experts and representations from NGOs and other stakeholders;
- to make appropriate recommendations for consideration of the GEAC based on the above review.

# Bt Brinjal cleared by Indian regulators includes....

- MHB 4 Bt, MHB 9 Bt, MHB 10 Bt, MHB 80 Bt, MHB 99 Bt, MHB 11Bt, MHB 39 Bt and MHB 112 Bt developed by M/s Mayhco (all 8 are hybrids)
- Malapur local (S) Bt, Manjarigota Bt, Rabkavi local Bt, Kudachi local Bt, Udupigulla Bt, GO112 Bt by UAS-Dharwad
- Co2-Bt, MDU1-Bt, KKM1-Bt, PLR1-Bt by TNAU, Coimbatore.

# MAIN CONCERNS WITH BT BRINJAL AND ITS CLEARANCE IN INDIA

# Main Concerns with Bt brinjal....

1. Rigging of the EC2 & its report
2. Need for, & relevance of Bt Brinjal
3. Health risks with Bt Brinjal and their evaluation
4. Environmental risks with Bt Brinjal & their evaluation
5. Lessons from Bt Cotton in India
6. Socio-economic implications of Bt Brinjal and its approval

# 1. EC 2 RIGGED FOR APPROVAL

# EC2 Constitution

1. Prof. Arjula R. Reddy, Vice Chancellor, Yogi Vemana University, Hyderabad and Co-chairman,

GEAC (Chairperson of the EC2).

2. Dr Vasantha Muthuswamy, Former Chief (BMS), ICMR, New Delhi: Member

3. Dr. B. Sesikaran, Director, National Institute of Nutrition, Hyderabad: Member

4. Dr. Lalitha R. Gowda, Scientist, CFTRI, Mysore: Member

5. Dr. N. Madhusudan Rao, Deputy Director, CCMB, Hyderabad: Member

6. Dr. C. M. Gupta, Former Director, Central Drug Research Institute, Lucknow: Member

7. Dr S. B. Dongre, Director (F&VP), Food Safety and Standards Authority (FSSA), New Delhi -

(Representative of MoH&FW): Member

8. Dr. Dhir Singh, ADG (PFA), FSSAI - (Representative of MoH&FW): Member

9. Dr. K. Satyanarayan, Scientist G, ICMR, New Delhi: Member

10. Dr. Dharmeshwar Das, Director, Indian Veterinary Research Institute, Izatnagar: Member

11. Dr. A. K. Srivastava, Director, National Diary Research Institute, Karnal: Member

12. Dr. Dilip Kumar, Director, Central Institute of Fisheries Education, Mumbai: Member

13. Dr. Mathura Rai, Director, Indian Institute of Vegetable Research, Varanasi: Member

14. Dr. P. Anand Kumar, Project Director, NRCPB, IARI, New Delhi: Member

15. Dr. K. K. Tripathi, Adviser, DBT, New Delhi: Member

16. Dr R Warrier, Director and MS GEAC: Convener

# EC2: Designed to approve?

- Chair admits to being under “tremendous pressure” – admitted to the need for long term tests and other tests which were missing
- Key regulator has a CVC complaint being examined – sat in the EC2 which was looking at Mahyco’s application
- One member who was part of ABSP II that developed Bt Brinjal, generated large scale trial findings and sat in EC2 to review his own findings
- Another member is a Bt Brinjal developer in IARI
- CIFE did a Mahyco-sponsored biosafety study earlier & then reviewed as part of EC2
- Two members were active in recasting of Indian safety assessment guidelines in the past with USAID’s funding!
- Two health ministry people as “OBSERVERS”

# EC2 – some issues

- Terms of Reference for the Committee changed from the January GEAC meeting to the actual constitution!
- Takes on mandate of assessing compliance with guidelines – principle of substantial equivalence being applied
- Compares with guidelines in countries like USA, Australia, Canada etc. – Does not compare specifically with Norway, Hungary etc!
- Guidelines have been re-cast with USAID support: do not adhere to GEAC's own discussions on the subject (85$^{th}$ meeting of GEAC accepts need for long term tests)
- EC1 recommendations overthrown without any scientific rationale even though there is a 1/3$^{rd}$ overlap in members of EC1 & EC2!!

# Main conclusion centred around…

- *"Raising the bar of the regulatory process as recommended by Dr. P.M.Bhargava based on hypothetical concerns and apprehensions would be highly detrimental for research and development in the area of agricultural biotechnology especially for public sector institutions and the benefits to the society at large"*
- *FORGETS THAT AGRI BIOTECHNOLOGY IS A VAST SUBJECT AND IS NOT TRANSGENICS*
- *FORGETS THAT MANY DEVELOPED COUNTRIES ARE ALSO BYPASSING TRANSGENIC TECHNOLOGY*
- *MAKES IT CLEAR THAT BT BRINJAL IS BEING EQUATED WITH GM TECHNOLOGY ITSELF IN ITS EVALUATION AND NOT EVALUATING BT BRINJAL ON ITS OWN MERITS AND DEMERITS!!*

# EC2 REPORT

- UNACCEPTABLE – LIKE DR PUSHPA BHARGAVA SAID, “BROUGHT DOWN INDIAN SCIENCE IN THE EYES OF THE WORLD”
- HELD NO IMPORTANCE IN THE MINDS OF CIVIL SOCIETY EVEN THOUGH GOVT WANTED TO CONSIDER IT AS AN IMPORTANT BODY WITH A RELIABLE RECOMMENDATION
- IT WAS FIT TO BE WITHDRAWN – WHICH MEANS THAT SUBSEQUENT GEAC CLEARANCE HAD NO BASIS EITHER….

# 2. IS THERE A NEED FOR BT BRINJAL?

# Claims for Bt Brinjal

- “High pesticide usage right now on Brinjal”
- “Pesticides causing a lot of havoc”
- “Bt Brinjal will reduce pesticide usage and pest damage by controlling the Fruit & Shoot Borer through a new toxin produced inside the plant with the insertion of the bacterial Bt gene”
- “Bt Brinjal will increase yields by reducing crop loss to pests”
- “Bt Brinjal will cut costs and improve farmers’ incomes”

# Reality Check…

- Most brinjal production in India does not use the kind of pesticide use that is being projected by the proponents
- Brinjal pest management is possible through numerous other practices that don't require chemical pesticides either. This is part of published scientific as well as field level evidence. For instance, just the use of pheromone traps on a large scale is supposed to be quite effective.
- The same rationale of talking about 'high pesticide usage' was used for bringing in Bt Cotton also. Today, it is clear that insecticide usage in cotton in India is higher (both in overall volume as well as intensity of use per acre) than it was in 2002 when Bt cotton was allowed.
- In fact, it is not just chemical pesticide usage that is higher in Bt cotton now, but also chemical fertilisers too.

# Plenty of other non-chemical pest management options

- NARS studies across the country show this possibility
- The CMSA experience in AP on 20 lakh acres demonstrates this
- The integrated pest management (IPM) strategy for the control of eggplant fruit and shoot borer (EFSB) consists of (conventional) resistant cultivars, sex pheromone, cultural, mechanical and biological control methods: World Vegetable Center – AVRDC 2000-2005
- It includes withholding pesticide use to allow proliferation of local natural enemies for pest suppression (Srinivasan, 2008)

# Unsustainable pest management options…

- Bt Brinjal is portrayed as part of an IPM approach – breaks many principles of IPM, however
- How can pest management for different pests across different crops in millions of acres be brought down to one gene?
- Is a farmer looking for one solution each for each pest or an integrated approach to pest management?
- Pest resistance is a reality being reported now on a wide scale on Bt cotton too

# Bt Brinjal pest management efficacy evaluation

- An evil compared with another evil – Bt with chemical pesticides!
- Not even IPM practices were followed in the trials
- This, despite express recommendations by the EC1 thus:

"*The EC-I further opined that the short term data generated on the environmental safety and socio economic aspects needs to be further substantiated with additional trials/tests to explicitly conclude the benefits from Bt brinjal and superiority of the technology with respect to existing technologies <u>especially the available methods for pest management and pesticide reduction</u>*".

# 3. HEALTH RISKS WITH BT BRINJAL

# Known health impacts of GM foods

- GM foods, including ones that have used Bt genes, have been shown in scientific studies to cause allergies, immune system damage, damage to internal organs like kidneys and liver, adverse impacts on growth and development, reproductive health interference etc.
- GM foods are also known to have altered nutrient compositions, compared to their non-GM counterparts
- Bt Brinjal is the only vegetable in the world with the Bt gene in it…
- Decision-making has to be based on proper biosafety assessment because assessing impacts in real life situation after allowing it into the food chain is extremely challenging

# Bt is not proven safe....

- Bt external sprays have not been proven safe either...In Bt crops, the endotoxin is produced 24X7 in all parts, in 1000-fold higher concentration!
- In fact, the mode of action of Bt toxin is not yet known to scientists and it is known to bind to mammalian cells too, other than impacts on non-target organisms...
- Bt Brinjal has a chimeric gene (not Cry1Ac) and this chimeric protein's safety has not been proven – in fact, all studies cited for Cry1Ac safety do not apply here!

# Cry1Ac protein-expression

- Expression of Cry1Ac protein and its quantification:“The levels of Cry1Ac protein were found to vary between 5 to 47 ppm in shoots and fruits”, notes the EC2 report. “Mean molt inhibitory concentration (MIC95 for *Leucinodes orbonalis* has been calculated to be 0.059 ppm for Cry1Ac”.
- In May 2007, the Director, Department of Animal Husbandry (AHD), Andhra Pradesh, sent a letter to the GEAC (ref: No 3531/Epid/2006.dated 9/5/2007), where he reported : “the Bt protein levels detected in the samples of Bt cotton bolls and leaves sent for analysis to different laboratories was recorded as 5 microgram/gm. This level is within the tolerable range which is said to be “5-10 microgram/gm”. On this basis, it justified that this level of protein expression in Bt Cotton is tolerable for sheep/goats. **In such a case, this clearly shows that the Bt protein far exceeds the “tolerable range” in Bt Brinjal.**

# Major findings of independent analysis of Bt brinjal biosafety dossier:

Parameters affected in animals fed with Bt Brinjal are in blood cells or chemistry and in different ways according to the period of measurement during the study or the sex:

**In goats** prothrombin time is modified, and biochemical parameters such as total bilirubin and alkaline phosphatase are also changed, as well as feed consumption and weight gain.

**For rabbits** less consumption was noted and also modification in prothrombin time, higher bilirubin in some instances, albumin, lactose dehydrogenase and the hepatic markers alanine and aspartate aminotransferases. Sodium levels were also modified, as well as glucose, platelet count, mean corpuscular haemoglobin concentration and haematocrit value.

# Other findings…

- **In Cows,** milk production and composition were changed by 10-14%. There was more milk and more roughage dry matter intake as if the animals were treated by a hormone.
- **In Rats,** GM-fed rats had diarrhoea, higher water consumption, liver weight decrease as well as relative liver-to-body-weight ratio decrease.
- **In broiler chickens**, feed intake as well as glucose in some instances were modified.
- **In GM-fed fishes**, average feed conversion and efficiency ratios were changed.

# Dr Lou Gallagher's analysis

- Departures from Indian and international published standards for the 14-day and 90-day studies cause alarm
- The single test dose used was lower than recommended by the Indian protocols. Other lower standards include: skipping important endpoints such as IgE measurement to test for allergenicity, ignorance of toxicological equivalence, lost data, lack of Good Laboratory Practice standards, inadequate observation of animals, a 29% decrease in exposure days in one study (doses were administered 5 days per week instead of 7)
- Concentrations of the new insecticide protein Cry1A(c) were not measured in dried brinjal powder. Important to know how much of it was actually in the dried samples fed to the rats, especially since data suggests that Cry1A(c) is at least partially destroyed in laboratory heating conditions.
- Food safety studies for Bt brinjal were not conducted in accordance with published standards, did not accurately summarize results, and ignored toxic endpoints for rats fed Bt brinjal. Rats fed a Bt brinjal for 78 out of 90 days (only one dose level) experienced:
  - *organ and system damage: ovaries at half their normal weight, enlarged spleens with white blood cell counts at 35 to 40 percent higher than normal with elevated eosinophils, indicating immune function changes.*
  - *toxic effects to the liver as demonstrated by elevated bilirubin and elevated plasma acetylcholinesterase*

# Dr Judy Carman's analysis

- Sample size of only 3 Bt brinjal and 3 non-BT brinjal were used to determine the differences in composition between the GM and non-GM brinjal. This is woefully inadequate to determine compositional differences between two crops.
- Compositional comparisons presented by Mahyco concentrate on measuring moisture, protein, oil, ash, carbohydrates, calories for fruit tissue, nitrogen, ash & crude fibre. These are extremely crude measures of brinjal's nutritional components. Full protein analysis would have gone some way to determine if plant was producing more, or less, of something, or a completely new substance. It was not done.
- Only real way of comparing the composition in this manner is to grow the GM & non-GM parent brinjal from which the GM brinjal was developed, side-by-side in the same field, under the same conditions of soil type, fertilizer, water, etc, and then using samples from these plants in comparison studies. Only then can any differences between the GM & non-GM crops be determined to be due to genetic insert and not due to confounders such as soil type, fertilizer, water, etc.
- No work done on whether the concentration of harmful components of Bt brinjal increase under different climatic conditions, eg heat or water stress.
- Did not provide any reproductive studies, even though adverse reproductive effects have been found from eating other GM crops
- No studies undertaken to determine if GM DNA in Bt brinjal can degrade on cooking.
- Acute toxicology test on mice not done using GM proteins as expressed in Bt brinjal.

# Dr Jack Heinemann

- Mahyco had not eliminated the possibility that there is more than one insertion of recombinant DNA and that all insertions are not free of vector “backbone” DNA. The Southern blot analysis is fundamentally flawed and incapable of finding unexpected inserts.
- Mayhco has not provided information on potential novel RNAs and proteins produced in the six possible open reading frames created by the EE-I event or by undetected secondary insertions. In fact, Mahyco has provided no information whatsoever on novel RNAs.
- Mahyco’s collaborator, Monsanto, can and does profile both transcriptomes and proteomes. These procedures have not been cost prohibitive for the industry, are rapidly becoming less expensive and do provide useful information.
- Nowhere in the Bt brinjal dossier is it clearly mentioned what was the comparator used in the tests, and whether Codex guidelines were being followed….
- “In my opinion, the dossier and the subsequent GEAC analysis (ECII) fail to meet fundamental and even routine hazard assessment standards for molecular characterization. Since this is the starting point of any risk assessment, the downstream effects on the analysis can be significant”.

# Dr David Schubert

- If GM food did cause an illness, it would not be detected because of lack of epidemiological studies and technical limitations for detecting such an illness.
- Many environmentally caused diseases take many decades of exposure to develop symptoms.
- No way of monitoring adverse health effects caused by Bt brinjal if it is commercially released.
- US agencies that allowed for introduction of Bt food crop did not require demonstration that GM food was safe for human consumption.
- Atleast 4 mechanisms by which introduction of Bt toxin in brinjal genome can cause harm –
  - *Random insertion of Bt gene into plant DNA and resulting unitended consequences – instance being discovery of synthesis of 9 known carcinogens caused by GM tobacco (a crop in same plant family as brinjal)*
  - *Alterations in crop metabolism by Bt protein which result in new, unintended and potentially toxic products – instance being abnormally high levels if fiber molecule lignin produced in Bt maize.*
  - *Direct toxicity of Bt protein*
  - *An immune response elicited by the Bt protein*

# Bt Brinjal sub-chronic testing: Rabbits

- As per Report of Study No. 4418/05, dated 14/7/2006, as contained in Volume 3 of Bt Brinjal biosafety dossiers on the GEAC website:

"6. Haemotology: There were no changes observed in between Control Non Bt Brinjal (G2) and transgenic Bt Brinjal containing Cry1Ac gene (G3) groups *except for an incidental but not biologically significant* reduction in platelet count in G3 males at interim blood sampling and significant increase in Hct, reduced MCHC in G3 males and increased prothrombin time in G3 females at terminal blood sampling".

"7. Clinical Chemistry: There were no changes observed in between Control Non Bt Brinjal (G2) and transgenic Bt Brinjal containing Cry1Ac gene (G3) groups *except for an incidental but not biologically significant increase* in albumin, and total bilirubin in G3 males and increased total bilirubin, lactose dehydrogenase in G3 females at interim blood sampling and *significant increase* in the AST, ALT, Total Billirubin and Sodium levels in G3 males and increased total bilirubin and *decreased* glucose levels in G3 females at terminal blood sampling".

- Report of Study No. 4417/05 (page 17 of 131), contained in Vol. 4 of the Biosafety Dossier of Bt Brinjal on the GEAC website has the following: "*There was significant difference in the hay consumption of the transgenic Bt Brinjal and control non-Bt Brinjal fed groups* and the control normal diet group except for incidence of lower hay consumption in G3 group males as compared to G2 group during week 11. *The change is considered to be marginal and considered to be of no physiological significance"*
- Haemotology: "There was no significant difference in the haemotological parameters between the transgenic Bt Brinjal and control non-Bt Brinjal fed groups *except for incidental change* in the value of prothrombin in G3 group males at termination". The prothrombin time for G3 group was 21.47 seconds with the difference with control groups being statistically significant but justified as being within the range of historical control values (prothrombin time – 11.8 and 21.6 seconds). The results could easily have been OUTSIDE this range and one can only guess how the crop developer would have justified the statistically significant changes even in this case.
- Clinical chemistry parameters: "There were no significant differences in the clinical chemistry parameters between transgenic Bt Brinjal and control non-Bt Brinjal fed groups *except for incidental changes* in the values of total bilirubin and alkaline phosphatase in G3 group males at termination".

# Conclusions unreliable....

**Crop Developer's dossier said**:

- In several "These changes are considered incidental and not related to transgenic Bt Brinjal feeding since the changes were marginal and of no biological significance". Beyond this, no rationale is available or provided.

**SC TEC SAID:**

- There are serious deficiencies in reporting of the data in the dossiers and more importantly in the way in which these have been examined and the conclusions accepted by the Regulatory Body. The deficiencies are serious enough that several of the dossiers are unlikely to meet international guidelines.
- The regulator has frequently accepted conclusions on health safety in the dossier regarding absence of a difference between Bt and non-Bt studies based on incompletely reported data or without appropriate statistical analysis, to the point of missing a difference where one does exist.
- There is a need to include chronic and transgenerational toxicity testing in feeding studies of rodents based on the fact that food is consumed over the entire lifetime and that nutritional stress can also lead to adverse or unintended effects over longterm exposure. The sensitive stages of reproduction also need to be included.

# Health concerns....

- Bt brinjal produces a protein which can induce resistance towards at least kanamycin, a well known antibiotic.
- The longest toxicity tests which are for only 90 days do not assess long-term effects like the development of tumours or cancers.

# Antibiotic resistant genes

- On antibiotic resistant genes, the EC2 only talks about how low the production of the enzyme of the AR genes is and therefore, no effect on antibiotics. The issue is that of horizontal gene transfer,  however…
- AR genes are to be treated differently in India, irrespective of the regulatory situation in other countries: antibiotic resistance is already a major issue for many diseases
- In the case of Bt Brinjal, HGT was not studied and EC2 denies that HGT occurs, despite a vast scientific body of knowledge on the subject!

# With Bt Brinjal…safety testing

- Several tests recommended by scientists have not been taken up as part of safety evaluation
- Further, protocols of tests that have been done are questionable – simple things like inadequate sample size to assess statistical significance properly; or test material doses being wrong…
- Analysis and interpretation also incorrect – no statistical analysis for some tests; significant differences discounted (sub-chronic 90-day studies in rabbits and goats have shown up differences even as per Mahyco)…
- Test materials have not even been authenticated!

# With Bt Brinjal … safety testing

- No independent research
- Not all studies in NABL accredited labs
- Apart from some international experts, no independent analysis of the raw data to this day
- No long term tests – no studies to assess carcinogenicity, reproductive health implications, endocrine disruption etc.
- Further studies, analysis and audits recommended by EC1 also not performed!

VERY CLEARLY, BT BRINJAL CANNOT BE CONCLUDED TO BE SAFE. IF AT ALL, IT IS UNSAFE, AS PER COMPANY'S OWN DATA…..

# 4. ENVIRONMENTAL RISKS OF BT BRINJAL & THEIR ASSESSMENT

# On pollen flow studies

- Brinjal classified as “often-cross-pollinated” crop – literature cited by EC2 shows *upto 48% outcrossing*
- First set of pollen flow studies taken up in 2002, even as backcrossing was underway!
- Pollen flow studies did not happen in the number of locations recommended by EC1
- Pollen flow would obviously depend on insect activity in this case and no conclusions can be drawn on sparse data

# On pollen flow …

- Claim of 0.14% (IIVR) to 2.7% (Mahyco) outcrossing questionable
- “Bt pollen travelled upto 20m (Mahyco) and 30m (IIVR)” virtually means that all neighboring non-GM brinjal plots will certainly get contaminated in India given our small holdings
- This is quite apart from other ways of mixing up (non-biological contamination)
- WHAT ABOUT THE RIGHTS OF FARMERS WHO WANT TO BE GM-FREE/ORGANIC? What about implications on existing diversity?

- “The issue of commercial release should not be discussed without a guarantee from Mahyco that there will be no contamination”
- Heirloom varieties need to be protected and reduction in biodiversity intentionally or unintentionally goes against the basic principles of CBD, Biological Diversity Act and PPVFR

# On Crossability

- Inter-specific hybrids have been experimented on all over the country – this is dependent on crossability, obviously
- Bt Brinjal crossability was tested mainly with *S. indicum.* There are several other *Solanum* species all over the country and studies in various universities which show crossability
- How can the conclusion of “no crossing was possible with representative wild varieties except *S. incanum* where limited crossing could be achieved” be accepted as the result of the crossability study given the existing other evidence?

# On soil impacts…

- Existing knowledge points to persistence of the Bt protein in the soil, changes in soil microbial activity
- EC2 justifies that trials in more than 50 locations have been carried out since 2003 and “not a single instance of any impact on soil microflora has been noticed”!! If you don’t look, what will you notice?
- Scientific data shows transgenic plants decompose less in soil than non-transgenic plants. Indian studies exist on Bt Cotton & soil impacts (IARI (published) and UAS-Dharwad (unpublished))
- The IIVR study found no traces of the Bt protein in the soil samples – this simply does not fit into any existing scientific knowledge on Bt protein’s persistence in soil – either the data is being falsified or the test protocols are completely wrong!
- The EC1 wanted study protocols to look at impacts on the next crop – not studied and no reason proffered for not studying!

# 5. LESSONS FROM BT COTTON IN INDIA

# Lessons from Bt Cotton cultivation

- Target pest has developed resistance, especially pink bollworm
- New pests and diseases have emerged
- Pesticide usage levels are higher now than levels that existed before the introduction of Bt cotton
- More chemical fertilizer usage now in cotton cultivation
- Cotton yields have stagnated and highest growth rates were in years when Bt cotton had not expanded in cotton cultivation
- Cotton diversity shrunk significantly
- Cotton seed monopoly in the hands of a MNC

# Lessons from Bt Cotton cultivation: Implications for the State

- No laws to regulate marketing and advertising of seeds, no scientific assessment of performance and for post-marketing monitoring
- Lack of regulatory capabilities showcased again and again – illegal HT cotton cultivation on a large scale; no redressal available for failures; no liability for violations
- Increased public financing burden – fertiliser use going up; need to cater to thirsty crops with more resources like watersheds, irrigation etc; HT cotton on one side, and NREGA on the other side!

# 6. SOCIO-ECONOMIC IMPLICATIONS OF BT BRINJAL

# Farmers' rights…

- Farmers' varieties being appropriated as corporate private property….
- Seed pricing exorbitant
- No liability regimes in favour of farmers – inadequate protection through consumer rights as seed consumers, for farmers
- No remediation mechanisms for eroded productive resources incl. soil fertility
- Farmers who wish to remain GM-Free or Organic – their rights violated
- Right to sustainable livelihood being violated too given all the various adverse health and environmental impacts of this technology

# Consumers' rights…

- Right to know what is being done to their food – there is not enough informed debate on the subject in the first instance!
- Right to have informed choices – even after getting some basic knowledge, if someone opts to eat or not eat GM, there should be choices
- Right to safe food – a very fundamental right…
- These will get violated with GM foods like Bt Brinjal coming in – a labeling regime will not work in India since most consumption is in an open manner – unpacked

# SOME IMPORTANT, GENERAL COMMENTS…

# Some other important issues....

- No crisis in brinjal production – food security cannot be the rationale
- External interference in regulation and GM crop development and conflicting interests being allowed willfully – highly objectionable
- Any comment of any expert that says that guidelines have been met, in a safety evaluation process, is unscientific – guidelines do not make a product safe or unsafe.
- Monsanto, which is behind all Bt Brinjal, is known for its anti-people, anti-farmer and even illegal behaviour – how are the regulators trusting only their data for decision-making?
- Any studies with surrogate proteins and with the wrong protein (Cry1Ac) will not be applicable in Bt Brinjal evaluation
- The adverse animal health impacts phenomenon observed in different states of India is not a close-and-shut case as the GEAC and others make it to be. There is much evidence which shows that willful falsified conclusions were drawn on this phenomenon.
- The EC2's attitude is unscientific when it equates biotechnology with transgenics and looks at transgenics as indispensable! On what grounds?

# Some general comments....

- Even backcrossing systems are unscientific and unreliable
- The callous attitude towards organic farming not acceptable
- No impact assessment on Indian Systems of Medicine taken up though brinjal and related species are used in ayurveda, siddha etc.
- No liability, redressal and remediation regime exists in the country – how can any GMO be approved in the absence of such mechanisms?
- What about state governments which do not want Bt Brinjal in their jurisdiction? Would it not be a violation of the state govt's constitutional right over its agriculture and health if the Centre still goes ahead with its approval?
- Any claim of "history of safe use" has to be proven by studies of an epidemiological nature ....
- Agriculture scientists are also wary of this product but there is a strange atmosphere where they are not ready to come out in the open and speak!

# Bangladesh is being used as the ground to bring in Bt brinjal....

- After India and Philippines rejected Bt brinjal, American lobby groups and funding pushed Bt brinjal cultivation in Bangladesh.
- Bangladesh started Bt brinjal cultivation in 2013-14 – 5 years later, less than 3% of the country's brinjal area is under Bt brinjal. No yield improvements as seen in proponents' hype about Bt brinjal are witnessed in any official data sets of Bangladesh.
- It is reported that seed stocks are lying while farmers are having to be lured to try Bt brinjal through various incentives provided including free inputs with seeds.
- Many reports related to crop losses due to Bt brinjal cultivation have emerged from Bangladesh.
- In fact, most farmers who have adopted Bt brinjal in the initial seasons have abandoned its cultivation.
- Furthermore, given that no labelling rules are being implemented, adverse impacts of consumption of Bt brinjal may not be known scientifically.....

# How Long this Patch-work Solution will last?

# THANK YOU