

# Bt Brinjal

Plethora of controversies Since 2005

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#### High incidence of pests in Bt Okra



New Delhi, Dec 27 | Updated: Dec 28 2005, 06:24am hrs

The Hyderabad-based Centre for Sustainable Agriculture (CSA) has found high incidence of several diseases and pest on Bt Okra under field trials in Narakoduru village in Guntur district, Andhra Pradesh.

The CSA team led by Gangadhar Vagmare, Ram Prasad and Kavitha Kuruganti found incidence of bacterial leaf spot, cercospora leaf spot, yellow vein mosaic, spotted bollworm, powdery mildew, spodoptera, jassids, aphids and white fly on Bt Okra developed by Mahyco. The CSA team noted that so far there had been four sprays of pesticide.

# Brinjal cultivation in India

- India is Centre of Origin as well as Centre of Diversity for brinjal
- India has about 29% of the world's brinjal cultivation area and contributes around 27% of the global production of brinjal
- 7.3 lakh hectares of cultivation, with average production around 126.5 lakh metric tons (135.6L MT in 2013-14), with productivity hovering around 17.5 to 18.5 MT/Ha
- 4<sup>th</sup> position amongst vegetables in India 7% in India's vegetable cultivation area and production volumes
- Cultivated in 12.32 lakh operational landholdings of India that many farmers estimated – mostly marginal farmers, but also under irrigation
- Largest areas are in West Bengal, Odisha, Jharkhand, Gujarat, Bihar, Madhya Pradesh and Chattisgarh in that order
- Yields are highest in Uttar Pradesh, Andhra Pradesh, Karnataka, Himachal Pradesh, Punjab and Bihar

# Brinjal yields in India

25.0

Brinjal Yield in India T/Ha



Compiled from National Horticulture Board's Horticulture Database, Ministry of Agriculture and Farmers' Welfare



More than 3600 accessions



# Brinjal Fruit and shoot borer





#### **Primary damage**



Shoot damage





- Attacks brinjal through out crop life time
- Damage range from 5-50%
- Monophagous pest-only on brinjal (like pink bollworm in cotton and stemborer in paddy



Paddy Stem borer



**Cotton Pink Bollworm** 

# Bt Brinjal...

- US agencies like USAID, Cornell University and Monsanto behind Bt Brinjal's development
- Open air trials from 2004 in different states
- Serious biosafety violations from field trials documented
- GEAC's guidelines violated when large scale trials were permitted in 2007, without biosafety being cleared first.....

# 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
- 7. TEC of SC cautioned against GM of crops having centre of diversity in India. And Bt in food crops
- 8. PSC recommendations

#### What do Bt Brinjal Biosafety data say?

- Independent analysis by Dr. Serelinii, Dr. David Andow both point out to problems with data
- No independent analysis was done
- Crop developers were in approval committee
- 10 state governments said NO
- Two agriculture universities said NO
- Two Horticulture university said NO

#### **Opinion of various states for Commercialization of Bt. Brinjal in India**

(Feb. 2010)



Remained silent



Rejected or Raised concern

Regulatory system:

corrupt systems and conflicts of interests

- Vice chair of GEAC was on the board of ISAAA
- EC-I headed by deepak pental who is developing GM crop
- EC-II chair said he was under pressure
- Indian Science Academies reports copied

What did the first independent analysis find?

 Several differences found between study and (closest) control groups in the Bt Brinjal biosafety tests were not reported in the summaries of the test reports but are in the raw data; statistically significant differences that were reported were discounted rather than used to raise food safety concerns or as warranting further investigations, as Prof Seralini points out. Prof Seralini's analysis points out that the interpretation of results in many cases by Mahyco is not scientifically acceptable.

## Bt Brinjal biosafety...

- Biosafety data apparently presented to regulators in 2006 itself....an expert committee gave its report in 2007
- Data not shared with the public despite orders from the Central Information Commission under Right To Information – public interest more important than commercial interests, the CIC ordered
- Data finally put out after SC orders in August 2008

#### Prof Seralini & team in CRIIGEN: First independent analysis

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.

# Prof Seralini's analysis....

- 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.
- **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.
- 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.

# 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

- 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".

# Dr David Andow

- The Bt brinjal event EE-1 was an inferior and old product;
- The scope for evaluation of Bt brinjal set by EC-II was too narrow; many of the environmental risks of Bt brinjal had not been considered;
- The risk of monophagous peststt developing resistance was very high, but this had not been addressed nor had any risk mitigation strategies been put forward;
- India was the centre of brinjal biodiversity with 29 wild varieties which were potentially at significant risk of contamination by Bt brinjal;
- The Bt brinjal hybrid was not suitable for resource-poor brinjal farmers with smallholdings; and
- no socio-economic analysis had been done to evaluate the effects of adopting Bt brinjal

# 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!

# KEY TAKEAWAYS FROM THE BIOSAFETY TESTING

- TESTS WERE NOT DONE EVEN THOUGH ASKED FOR BY EC I
- TESTS USED WRONG PROTOCOLS AND DESIGNS
- TEST RESULTS WERE NOT ANALYSED PROPERLY
- SIGNIFICANT DIFFERENCES WERE FOUND IN SEVERAL STUDIES DATA SHOWS SOMETHING, AND CONCLUSIONS MADE WERE SOMETHING ELSE – REPORTING WAS SOMETHING ELSE

IT IS NOT JUST THAT IT IS NOT SAFE, BIOSAFETY DOSSIER SHOWS THAT IT COULD BE UNSAFE....

#### EC2 Constitution

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"

#### Lessons from Failed Bt Cotton cultivation (Technology)

- 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,
- Disappearance of non-Bt seeds from the market
- Cost of cultivation increased, profitability reduced
- FAILURE OF A UNSOUND SCIENCE OF PLANT PROTECTION, WHICH IS BASED ON A MOLECULE, NOT SYSTEM

# 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!

# 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



#### Can there be a choice to consumer?

- Labelling still to be put in place
  - How primary products like vegetables would be labelled ?
  - Who is accountable ?
  - In a country with more illiteracy how to implement ?

#### Problems with detection due to

- Degradation of DNA
- High degree of processing
- Low amount of ingredient
- Highly Processed food
  - May contain GMOs (oil, starch, glucose syrup)
  - Detection not possible, no DNA left after processing
- Mixed processed food
  - May contain GMOs in flour, or any other ingredient (e.g. cheese)
  - Detection possible but in most cases very complicated, time consuming and expensive



The report of the Expert Committee (EC-II) submitted to the GEAC on October 8<sup>th</sup>, 2009 that formed the basis of the GEAC'as decision of October 14<sup>th</sup>, 2009 is being made public with immediate effect. It is being uploaded straightaway on the website of the Ministry of Environment and Forests (<u>www.moef.gov.in</u>). All previous reports and studies on Bt-brinjal are already in the public domain. Comments on this report are being sought by December 31, 2009 and I encourage their submission.

During January and February 2010, I propose to have a series of consultations in different places with scientists, agriculture experts, farmers' organisations, consumer groups and serious-minded NGOs who want to engage in a responsible manner. All points of view will be represented in these consultations.

## Public hearing 2009



#### Moratorium

it is my duty to adopt a cautious, precautionary <u>approach</u> and imp<u>ose</u> principle-based moratorium on the release of Bt-brinjal, till such time independent scientific studies establish, to the satisfaction of both the public and professionals. <u>the safety of the product from the point of view of</u> <u>health</u> long-term impact on human and its environment, including the rich genetic wealth existing in brinjal in our country.

28. The moratorium period should also be used to operationalise the independent regulatory body in its entirety as being recommended by many scientists as well as civil society organizations. I also hope in the moratorium period we give serious thought to the strategic importance of the seed industry<sup>15</sup> and how we retain public and farmer control over it even as we encourage private investment in agricultural biotechnology. I would also recommend that the moratorium period be used to have a detailed debate in Parliament and also a comprehensive discussion in the National Development Council (NDC) on this subject.

30. I expect the GEAC to take follow-up action on the matter of further studies and tests with appropriate protocols and in appropriate laboratories. I also expect the GEAC to carefully study all the material I have received and am turning over to it. I would like the GEAC to engage and interact with all those scientists. institutions and civil society groups who have submitted written representations to me. The GEAC should consult with scientists like Dr. M.S. Swaminathan, Dr. P.M. Bhargava, Dr. G. Padmanabhan, Dr M. Vijayan, Dr. Keshav Kranthi, Dr. Madhav Gadgil and others to draw up a fresh protocol for the specific tests that will have to be conducted in order to generate public confidence. Under no circumstances should there be any hurry or rush. The moratorium will continue for as long as it is needed to establish public trust and confidence. Meanwhile, I also intend to change the name of the GEAC from Genetic Engineering Approvals Committee to Genetic Engineering Appraisal Committee.

### Post Moratorium

- THIS IS A TECHNOLOGY THAT IS GOING AROUND LOOKING FOR A PROBLEM-Jairam Ramesh
- NEED & ALTERNATIVES ASSESSMENT
- SCIENCE ACADEMIES REPORT
- STANDING COMMITTEE,
- Supreme Court appointed Technical Committee
- RENUKA CHOWDHARY COMMITTEE

#### Plenty of other non-chemical pest management options

- NARS studies across the country show this possibility
- The NPM experience in AP and research by Natural Resources Institute UK have proven NPM approach
- 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)

# NPM for Brinjal FSB

- Continuous cropping of brinjal on the same piece of land should be avoided.
- Deep summer ploughing before the season or once the crop is harvested to expose the resting pupae in soil.
- Bon-fires with the onset of first showers
- Potato, voluntary brinjal plants (those brinjal plants which are germinated on their own) and other wild brinjal plants act as alternate hosts have to be removed.
- Intercropping with coriander reduces incidence by more than 50 %

# Mass trapping

- Mass trapping of adults using pheromone traps reduce the chances of female moths finding a mate
- Research by AVRDC suggests that female *L. orbonalis only mate once and from other* research we know that even delayed mating can significantly reduce the number of viable eggs female moths can produce (fecundity)
- A range of designs of traps has been found to be suitable for *Leucinodes orbonalis*.
- Water traps prepared from plastic bottles are recommended (40 pheromone traps(5m apart) per acre kept 1 ft above the crop height and the lures have to be changed at 20 days interval
- If it is taken on community basis, the number of pheromones by each farmer could be reduced.





# Brinjal FSB management

- As soon as the insect is detected, the affected parts should be clipped along with the insect and destroyed
- Fruits showing any boring symptoms should be picked and destroyed.
- Spraying neem oil @25ml per litre of water during vegetative stage will prevent the moth laying eggs on the crop. This may be taken when the pheromone catch is observed.
- To prevent neonate larvae boring into the fruit or shoot, Neem seed kernel extract (NSKE) 5% or *agniastra* may be sprayed.
- Chilli-garlic extract may be used to control shoot and fruit borer; but this has to be used only twice during crop period. 5 days after using chilli-garlic extract, cowdung-urine solution has to be used
- These sprays are necessarily be done in the evening times.

#### **Center for Sustainable Agriculture**

CSA

& Grameen Academy presents



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