

# A New Bt Brinjal Threat (“Event 142”) is Looming Large on India...

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# Subsequent to the moratorium decision....

- 6 academy of sciences did not come up with anything substantial other than draw some controversy onto themselves
- 680 kgs of Bt brinjal seed left with Mahyco and not deposited with NBPGR
- Not a single additional study was undertaken by Mahyco to show that Bt brinjal is safe or needed since 2010. When Mahyco applied for “large scale environmental release/ demonstration” of Bt brinjal and GEAC discussed the same in its [136<sup>th</sup> meeting](#) in Sept. 2018, instead of going back to the moratorium decision note, GEAC decided to obtain relevant information & data on post-commercial release effects of Bt brinjal from BARI! And to get independent study reports from the company about Bt brinjal in Bangladesh. Coalition [objected to this](#).
- Right after the moratorium decision, in the very second meeting that GEAC had, in [May 2010](#), it concluded that moratorium on Bt brinjal has no implication on the proposal for BRL I trials of another Bt brinjal and approved the same. **THIS IS BT BRINJAL EVENT 142** (subject of this presentation).
- April 2019 – Bt brinjal illegal cultivation in Fatehabad in Haryana – NBPGR confirmed that it is GM brinjal, but ruled out Mahyco’s event – **IS THIS EVENT 142 then?**

# Bt Brinjal “Event 142”

- Created by National Research Centre for Plant Biotechnology (NRCPB) in Indian Agriculture Research Institute (IARI) in ICAR
- [Dr Polumetla Ananda Kumar](#) is supposed to have developed this event. He was one of the scientists who was part of the [Bt Bikaneri Narma controversy](#) wherein the so-called BNLA 106 Event (developed by Ananda Kumar) turned out to be Monsanto’s MON531 event in cotton. He developed another Bt brinjal also and [field tested it in 1995!](#)
- Patent No. 237912 granted in 2010 with IARI as patent holder and Dr Ananda Kumar as the inventor
- Ananda Kumar was earlier in RCGM as well as GEAC as a regulator in [2006](#), [2007](#), [2008](#), [2009](#), [2010](#), and till [July 2011](#) when he resigned even though he is a GM crop developer himself. He was part of EC1 and EC2 for Mahyco’s Bt brinjal and carried his conflict of interest there too.
- B Sesikeran who was with NIN, who was also a member of GEAC when the toxicity data of this Bt brinjal was being discussed by the Committee explained the findings of the study to the Committee!
- In 2010, controversy in the inter-academy report where material from some publicity article was copied and pasted (“Bt Brinjal: A Pioneering Push”, published in December 2009 in “Biotech News”, written by Dr Ananda Kumar), and defended by Dr Kumar as his inputs for the report

# Event 142

- Chimeric Cry1Fa1 gene - Domain I having a first native *Bacillus thuringiensis* delta-endotoxin Cry1Aa, Domain II having a second native *Bacillus thuringiensis* delta-endotoxin Cry1Ac protein and Domain III with a third native *Bacillus thuringiensis* delta-endotoxin Cry1F protein.
- Cauliflower Mosaic Virus CaMV35S as a promoter
- Octopine Synthase (OCS) as a terminator sequence
- NptII or neomycin phospho transferase gene from E.Coli
- *The chimeric protein is 624 amino acids in length and is a unique  $\delta$ -endotoxin.*
- *DNA sequences of the native Bt structural genes (cryIAa, cry1Ac and cry1Fa1) were modified in order to contain codons preferred by highly expressed plant genes, to attain an A+T content in nucleotide base composition substantially that found in plants, and to eliminate sequences that cause destabilization, inappropriate polyadenylation, degradation and termination of RNA and to avoid sequences that constitute RNA splice sites*

# Event 142

- Transformation method: Agrobacterium mediated
- Plasmid vector used: pBinAR
- Promoter – CaMV35S; Terminator – Ocs
- Antibiotic resistance marker – npt II with Nos promoter & Nos terminator

# PPP deal between NRCPB & private companies

- NRCPB developed
- Licensed to private companies for biosafety testing and commercialization
- Bejo Sheetal, Vibha Seeds, Nath Seeds and Krishidhan Seeds – Rasi Seeds also did trials with this Cry1Fa1 gene...
- **OTHER DETAILS NOT AVAILABLE – APPLIED UNDER RTI**

# Progress of Bt brinjal Event 142

- [93<sup>rd</sup> meeting](#) of GEAC on 13/5/2009 gives permission for BRL1 trials in 3 locations – Jalna, Guntur and Varanasi
- [100<sup>th</sup> meeting](#) of GEAC on 12/5/2010 accorded 2<sup>nd</sup> year BRL I trials permission
- [119<sup>th</sup> meeting](#) of GEAC on 25/4/2014 – BRL2 application discussed since 2 years of BRL1 reported to be completed in 3 locations during 2009-10 – experts wanted time and wanted to look at biosafety dossier submitted thus far
- [121<sup>st</sup> meeting](#) of GEAC on 18/7/2014 – BRL2 Trials in 7 locations permitted - Maharashtra, Gujarat, Punjab, Haryana, Uttar Pradesh, New Delhi and Andhra Pradesh – go-ahead given *along with a sub-committee to examine the toxicity studies*
- [130<sup>th</sup> meeting](#) of GEAC on 11/8/2016 – information shared with members that GEAC Chairperson approved trial in an additional location – location not mentioned
- [139<sup>th</sup> meeting](#) of GEAC on 19/5/2020 – BRL-II trials reported to have been conducted during 2016-17 in Maharashtra, Gujarat, Uttar Pradesh, New Delhi and Andhra Pradesh. BRL2 trials for seasons 2020-23 approved in Madhya Pradesh, Karnataka, Bihar, Chattisgarh, Jharkhand, Tamil Nadu, Odisha and West Bengal.

**COPIES OF APPLICATIONS AND PERMISSIONS REQUESTED UNDER RTI DENIED BY GEAC**

# Regulator works out modalities for biosafety clearance!!

- [GEAC](#) holds a meeting on 27/10/2009 with technology provider and licensees to bring clarity on the modalities for generating biosafety data and sharing of responsibilities in getting biosafety clearance!
- M/s Bejo Sheetal would carry out all biosafety studies, be responsible for interfacing with regulatory agencies. Technology provider to continue studies if company unable to do so.
- All licensees enjoy equal status and parity, will have equal rights over all studies conducted by M/s Bejo Sheetal. Cost will be shared by all licensees
- Given the event based approval mechanism adopted in Indian regulation, data generated would be applicable to Bt brinjal hybrids/varieties developed by other licensees.



# Studies reported to have been completed

As per 121<sup>st</sup> meeting of GEAC held on 18/7/2014, following studies done:

- a. History of Safe use of Bacillus thuringiensis
- b. Safe use of Cry 1 F Protein.
- c. Mode of action of Cry1 Fa1.
- d. Safety assessment of Bt Brinjal carrying Cry1Fa1 gene, event 142.
- e. Test with Cry 1 Fa1 purified; Study Center: National Institute of Nutrition, Hyderabad. — Pepsin Digestive Assay. — Thermo stability. — Acute oral toxicity.
- f. Sub-chronic Feeding Test with Bt and non Bt Brinjal leaves and fruits. Study Center: National Institute of Nutrition, Hyderabad.
- g. Comparative studies on Soil Ecosystem of Bt and Non Bt Brinjal field. Study Center: Institute of Microbial Technology, Chandigarh.
- h. Detection of Cry1Fa1 protein in the soils of Bt brinjal trial fields.
- i. Comparative studies on compositional study of Bt and Non Bt brinjal study Center: Institute for Analysis of Dairy, Food and cultures, Bangalore.
- j. Pollen flow study.

# Studies asked for during Non Replicated BRL II testing

- Efficacy data of the Bt brinjal against target pest shoot and fruit borer (*Leucinodes orbonalis*).
- Information on yield and demonstrate agronomic performance of Bt brinjal hybrids as compared to their non-Bt counterparts and commercial check hybrids.
- Information on incidence of beneficial and non-target insects among Bt brinjal and their non-Bt counterparts.
- Information on insect infestation on Bt brinjal, their non-bt counter parts and non-bt commercial check hybrids
- Repeat Southern analysis in a single plant copy insertion to demonstration inheritance.

**DATA ASKED ON WHERE TRIALS HAPPENED & NOCs OF STATE GOVERNMENTS DENIED UNDER RTI**

# WHO IS THE APPLICANT IN THE REGULATORY FILES?

- **Bejo Sheetal Seeds Private Limited**, Jalna seems to have been the applicant in May 2009 when GEAC 93<sup>rd</sup> meeting gave permission. Same entity noted in minutes of 119<sup>th</sup> 121<sup>st</sup> and 130<sup>th</sup> meetings too.
- **Beej Sheetal Research Private Limited** received permission in 139<sup>th</sup> meeting
- Nothing in the GEAC meeting minutes to indicate that this change has been noted or permitted by GEAC
- Bejo Sheetal is a company that has **closed down**. It had a joint venture with Bejo Zaden of Holland.
- Links between Bejo Sheetal, Bejo Sheetal Bio Science Foundation, Beej Sheetal Inventions Centre, Kalash Seeds, Safal Seeds, Sheetal Hybrid Seeds etc. show a convoluted picture of the same small set of people opening and closing various entities to suit their business purposes.
- **From a regulatory perspective, accountability / liability-fixing is a difficult proposition – who is the responsible party for the PPP with IARI?**  
**INFORMATION ON GEAC PROCEDURES WHEN APPLICANT CHANGES DENIED UNDER RTI**

# Biosafety concerns reflected in studies

- Pollen flow studies during BRL I trials in 3 locations – unclear if even this was done – adequate?
- Efficacy trials obviously taken up vis a vis pesticides and not against agro-ecological practices – this applies to incidence of beneficial and non-target organisms too – similarly to soil ecology
- Acute oral toxicity study with Swiss Albino Mice showed 20% mortality upon administering of test compound Cry1Fa1 lyophilised protein orally at 2000 mg/kg body weight – “the histopathological changes observed in the lungs and liver of dead animals are common to colony bred animals and may not be attributed to administration of test compound” – when tests were repeated again in mice, there was no mortality
- Acute oral toxicity study with Sprague Dawley Rats, “the food intake and gain in body weight was not abnormal”.
- 90-day rat feeding study with leaves as well as fruit – one female rat from non-transgenic leaf fed group died on Day 38. Some statistically significant differences observed (in ??) were also “within normal range” and “were not found to be biologically significant”.

# Biosafety concerns...

- Lengthy discussions with 4 members of the Committee asking for change in protocols in toxicity studies.... A sub-committee was constituted to review the toxicity data but GEAC gave a go-ahead to BRL II trials – **DATA ON SUB COMMITTEE CONSTITUTION, ToR, FUNCTIONING AND FINAL REPORT BEING DENIED UNDER RTI**
- Range of normal variation and sample size of animals in the test – should a study be repeated for just that one parameter for which the first round of testing showed statistically significant difference - was just one dose used or multiple doses etc.
- Should we go strictly by guidelines which have already frozen some sample sizes, ways of interpreting results etc., or should they be reopened?
- **BIOSAFETY DOSSIER BEING DENIED UNDER RTI**

# NO INFORMATION IN THE PUBLIC DOMAIN

- MoU between IARI and companies
- What did the applications seek and what did the permission letters say –copies of applications & permission letters being denied!
- Where did the trials happen and did state governments give NOCs?
- What are the results of the trials and what does the entire biosafety dossier contain?
- What is the ToR and constitution of the sub-committee, and what did it have to say about toxicity studies?
- Did the BRL II trials get initiated after the sub-committee gave a go-ahead or did they commence without the sub-committee finishing its work?
- Were any tests re-done, and what are the results of the same?
- Who is the current applicant and what is the relationship with the earlier applicant legally? On what basis is GEAC entertaining the application? Who is liable for any violations and mishaps?

**WHAT WE DISCOVERED IN MAHYCO BT BRINJAL AND WITH SOME LITTLE INFORMATION IN THE CASE OF GM MUSTARD – THEY ARE CERTAINLY HIDING THINGS THAT THEY DON'T WANT US TO SEE AND KNOW**

# Whatever the “event”, key concerns remain

- Need for Bt brinjal? Case of technology going around looking for a problem?
- No consensus in the scientific community – responsible CSOs and eminent scientists raising many serious questions with no satisfactory answers
- Much opposition from state governments
- Public sentiment is negative
- Brinjal diversity heritage in India
- Brinjal consumed in numerous ways and not always cooked
- Brinjal use in ISM
- Consumer rights of knowing what they are eating and making informed choices
- Serious regulatory failures witnessed time and again – crop developers and biosafety assessors were both regulators and were driving the shape of regulatory regime – is this to be trusted?
- Illegal cultivation – regulatory failure – testing regime inadequate – labs not equipped to do event-specific testing – liability regime on event developer missing

FOR MORE INFORMATION:

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