

**GEAC IS GETTING WORSE IN ITS REGULATORY FUNCTIONING OVER THE YEARS:  
GM MUSTARD'S FARCICAL PUBLIC FEEDBACK PROCESSES, CONTRASTED WITH THE REGULATOR-  
ADOPTED PROCESSES FOR BT BRINJAL**

*(This is a quick note prepared by Kavitha Kuruganti to show the contrast between Brinjal & Mustard, tests on the transgenic versions of these crops and the regulatory processes adopted then and now; for any queries and corrections, you can contact [kavitakuruganti@gmail.com](mailto:kavitakuruganti@gmail.com))*

When Government of India placed Bt brinjal on an indefinite moratorium on February 9<sup>th</sup> 2010, it was with an explicit admission that the regulatory system was faulty, that the risk assessment regime was not robust and that the testing systems were highly inadequate. The government also explicitly said that while the moratorium was in place, there should be significant improvements in the regulatory systems. So, it is only natural that citizens expect that 6 years after the Bt brinjal moratorium decision, that there would be indeed be improvements in regulation when GM HT mustard application is being processed by the regulators. However, that is simply not the case. **Regulation has become worse, and we show you how.**

**BRINJAL Vs. MUSTARD IN INDIA**

BRINJAL	MUSTARD
We are the Centre of Origin & Diversity	We are a Centre of Diversity
Around 5 lakh hectares cultivation area	Around 65 lakh hectares' cultivation area
Production of around 8 million tonnes	Production of around 65-80 million tonnes
Mostly in West Bengal, Odisha, Bihar, Gujarat etc.	Mostly in Rajasthan, Uttar Pradesh, Madhya Pradesh, Punjab, Bihar, Haryana, Gujarat, Assam etc.
Consumption mainly of fruit	Consumption of seed, leaves and oil; seed cake fed to animals and as soil amendment
	Has Honey Production associated with the crop
Used in Ayurveda	Used in Ayurveda
Deep cultural significance in most parts of India	Deep cultural significance in most parts, including those that don't grow the crop in large quantum

**TESTS DONE FOR BT BRINJAL & GM HT MUSTARD**

Bt Brinjal Source: ECII Report (pp12-13) <a href="http://www.moef.nic.in/sites/default/files/Report%20on%20Bt%20brinjal_2.pdf">http://www.moef.nic.in/sites/default/files/Report%20on%20Bt%20brinjal_2.pdf</a>	GM HT mustard Source: AFES Document (Page 8, Table 1.2) <a href="http://www.moef.gov.in/sites/default/files/Safety%20assessment%20report%20on%20GE%20Mustard_0.pdf">http://www.moef.gov.in/sites/default/files/Safety%20assessment%20report%20on%20GE%20Mustard_0.pdf</a>
Field trials were allowed by different states except Bihar, Odisha, West Bengal	FTs not allowed by most states – only Rajasthan (which later destroyed a trial), Punjab & Delhi allowed. Now, they are also saying NO.
Environmental Impact Assessment	
Pollen flow studies: 3 years (2002, 2007, 2008)	Pollen flow studies ( <u>not done for parental lines</u> , but only for DMH-11): 1 year, 1 location
Germination & Weediness studies: 2 seasons (2002 and 2003)	Weediness potential: 3 seasons
Aggressiveness studies: 2 seasons (2002 and 2003)	Aggressiveness study: lab study on seed germination and seedling vigour
Soil micro-biota studies: 2 years (2003 and 2004); Soil microflora studies: 2 years (2007, 2008) – on	Impact on Soil Microflora: 3 BRL seasons – however, no earthworms and collembola impacts were

bacterial, fungal, earthworm and collembola populations	studied
Effects on non-target and beneficial insects: 2 years (2004 and 2005)	BRL trials: 3 seasons – we had already shown how the observations are untenable in nature!
Crossability study (2007-08, 2008-09)	Crossability study: 2010, one location
(Baseline susceptibility study in 2004, 2005, 2007, 2008)	Pollination behavior (3 seasons), pollen morphology and physiology (2 seasons)
<b>MOLECULAR CHARACTERISATION &amp; DETECTION PROTOCOLS</b>	
Molecular Characterisation and Event ID (2002)	Molecular Characterisation
Protein Expression Studies (2004, 2005, 2006, 2007)	Protein Expression Studies (1 contained net house and 3 BRL seasons)
Chemical Fingerprinting (2006)	Cloning, expression, purification and production of three expressed proteins
Event Specific Detection Method	Event Specific Detection Method
<b>OPEN AIR FIELD TRIALS FOR AGRONOMIC EVALUATION</b>	
RCGM MLRT: 11 locations (2004)	BRL I trials, 2 seasons (2010-11, 2011-12)
ICAR AICRP trials: Year I and II (2004 and 2005)	1 Year done, data not used in averages! (2006-07)
Large Scale Trials: 1 year (2007-08)	BRL II trials, 1 season (2014-15)
NOW, AFTER CIVIL SOCIETY EVIDENCE ON GM MUSTARD'S LACK OF YIELD SUPERIORITY, IT IS BEING SAID THAT YIELD RELATED AGRONOMIC EVALUATION IS NOT THE MANDATE OF GEAC!	
<b>HEALTH SAFETY ASSESSMENT</b>	
Acute Oral Toxicity Test in Rats (2003)	Acute Oral Toxicity in Swiss Albino Mice (Year NA)
Mucous Membrane Irritation Test in Female Rats (2004)	NOT DONE
Primary Skin Irritation Test in Rabbit (2004)	NOT DONE
Sub-chronic oral toxicity study in Sprague Dawley Rats (2005)	Sub-Chronic Oral Toxicity in Sprague Dawley Rats
Assessment of allergenicity of protein extract using Brown Norway Rats (2005)	NOT DONE; ONLY a Bioinformatics Analysis and Pepsin Digestibility Assay of the three proteins
Food cooking and protein estimation in cooked fruits (2005)	Thermal Stability done
Feeding study on Common Carp (2005)	NOT DONE
Sub-chronic feeding study using New Zealand Rabbit (2006)	NOT DONE
Effect on performance and health of broiler chickens (2006)	NOT DONE
Sub-chronic feeding studies in goats (2006)	NOT DONE
Feeding studies in lactating crossbred dairy cows (2006)	NOT DONE
Detailed Compositional Analysis (2008-09) including estimation of alkaloid content	Compositional Analysis of seeds and leaves, from BRL-I 1 <sup>st</sup> year trial plants, including glucosinolates estimation
Note: MANY OF THE STUDIES PRESCRIBED BY THE EXPERT COMMITTEE 1 AND THROUGH GEAC DECISIONS WERE ACTUALLY NOT TAKEN UP IN THE CASE OF BT BRINJAL!	Justification that regulatory processes are being improved with changed guidelines is untenable given the importance of this food crop, that this is a HT GM crop, where non-GM hybrids already exist)

## PROCESSES ADOPTED BY REGULATORS FOR BT BRINJAL & GM MUSTARD

Stage	GM HT mustard	Bt brinjal
<p><b>BEFORE</b> Large Scale Trials or BRL II trials</p>	<p>No Processes adopted for even internal review of any material by GEAC.</p> <p>From all information available, it appears that though they placed their deep appreciation at the way the biosafety dossier was compiled and submitted, there was no review taken up by GEAC in its 121<sup>st</sup> meeting on 18<sup>th</sup> July 2014 of the material supplied by CGMCP.</p> <p><b><u>This is a major lacuna in the process as we showed through other evidence – since there was no review, there was no detection of wrong protocols, wrong analysis, wrong conclusions that were drawn.</u></b></p> <p>From information that we have, it appears that GEAC itself has no access to any raw data to this day.</p>	<p>On 22<sup>nd</sup> May 2006, GEAC heard the presentations made by Mahyco on results of biosafety studies conducted and on an application to permit large scale trials. GEAC then decided that the biosafety data be posted on the MoEF website and comments received. <a href="http://www.moef.gov.in/sites/default/files/geac/geac-67.pdf">http://www.moef.gov.in/sites/default/files/geac/geac-67.pdf</a></p> <p>On 29<sup>th</sup> May 2006, MoEF uploaded a note on Bt brinjal and Mahyco's presentation on the website. <a href="http://www.moef.nic.in/divisions/csurv/geac/information_brinjal.htm">http://www.moef.nic.in/divisions/csurv/geac/information_brinjal.htm</a></p> <p>Subsequently they received requests for 90 days' public feedback time. <a href="http://www.moef.gov.in/sites/default/files/geac/geac-68.pdf">http://www.moef.gov.in/sites/default/files/geac/geac-68.pdf</a></p> <p>The time period for submitting comments was extended to 15<sup>th</sup> July 2006. <a href="http://www.moef.gov.in/sites/default/files/geac/geac-69.pdf">http://www.moef.gov.in/sites/default/files/geac/geac-69.pdf</a> ; <a href="http://www.moef.nic.in/divisions/csurv/geac/information_brinjal.htm">http://www.moef.nic.in/divisions/csurv/geac/information_brinjal.htm</a></p> <p>On 24<sup>th</sup> August 2006, GEAC constituted an Expert Committee on Bt Brinjal, BEFORE ALLOWING LARGE SCALE TRIALS. The Committee's ToR was to evaluate comments received from stakeholders, suggest additional studies if any, to evaluate the adequacy of the protocol proposed for LST, to recommend protocol for socio-economic studies and any other recommendations. The ToR also said that if considered necessary, the Committee may also invite and hear views of the stakeholders. <a href="http://www.moef.nic.in/divisions/csurv/geac/expert_penthal.htm">http://www.moef.nic.in/divisions/csurv/geac/expert_penthal.htm</a></p> <p>The first meeting was held on 25<sup>th</sup> September 2006.</p> <p>The Committee was re-constituted on 30/11/2006 when certain members did not come on board and join the Committee.</p>

		<p><a href="http://www.moef.nic.in/divisions/csurv/geac/expert_comm_301107.pdf">http://www.moef.nic.in/divisions/csurv/geac/expert_comm_301107.pdf</a></p> <p>When the Conflict of Interest of the Chair Dr Deepak Pental was pointed out by civil society groups, either he stepped down himself or was asked to step down. The Committee then worked with Prof C R Babu as its Chair and finished its work by 3/7/2007. Based on the EC-I's recommendations, GEAC in its 79<sup>th</sup> meeting on August 8<sup>th</sup> 2007 approved LSTs of Bt brinjal.</p> <p>The report of the Expert Committee (1) presents its ToR, constitution, methodology adopted and conclusions/recommendations clearly, unlike the AFES document in the case of GM mustard. The EC also answered the main comments received from public, theme by theme and point by point in its report. It also added numerous additional tests to be done and conditions under which the LST may be permitted.</p> <p>Here, the public were given 45 days' time for feedback, further extended later on by 15 more days.</p> <p>Points worth noting about this process:</p> <ul style="list-style-type: none"> <li>• External experts, who are non-GEAC members were brought on board into the Expert Committees. Dr Parasuraman of TISS for socio-economic impact analysis, for instance. And for designing protocols for assessing such impacts. THIS SHOWS A HUMBLE ACCEPTANCE THAT GEAC DOES NOT HAVE ALL THE EXPERTISE NEEDED AND THERE IS MUCH EXPERTISE OUT THIS REGULATORY BODY IN A VAST COUNTRY LIKE INDIA.</li> <li>• Data was put out, though incrementally, based on public pressure, as submitted by the crop developer (no screening or sanitization happened of such data).</li> <li>• <b>Collection of public feedback was done first, before</b> constituting a committee, and the committee took such comments on board apart from looking at all the available data itself.</li> <li>• The Committee's ToR was also around</li> </ul>
--	--	---

		<p>suggesting additional studies and improving protocols which they tried to do.</p> <ul style="list-style-type: none"> <li>• Public was given 45 days' time for feedback.</li> <li>• The Committee not only made its full report including methodology adopted public, but also responded to comments received to justify its decisions and recommendations.</li> <li>• GEAC discussed the Committee's main recommendations at every stage of the process, after each meeting of the Committee!</li> </ul>
<p><b>AFTERLSTs/ BRL II trials were also completed</b></p>	<p>GEAC forms an internal Sub-Committee in January 2016, after receiving an application in September 2015 from CGMCP and after hearing a personal presentation from Dr Deepak Pental in December 2015.</p> <p>This 7-member committee, also supported by the Member Secretary had its first meeting on 2<sup>nd</sup> February 2016 and submitted its report for consideration by GEAC on 5<sup>th</sup> February 2016.</p> <p>Subsequent processes were between this Committee and the Crop Developer and the whole process was undertaken as though no other independent scrutiny was necessary.</p> <p>The sub-committee's report never came up for review in the GEAC meetings (August 11<sup>th</sup> 2016). The sub-committee report is not the same as the AEFS document that has been put up for public feedback – the GEAC members did not receive or review such an AEFS document.</p> <p>Public are now being asked to comment on a pre-concluded AEFS document, not reviewed by GEAC itself, which incorporates</p>	<p>In the 91<sup>st</sup> meeting of the GEAC on 14/1/2009, it was decided to form an expert committee (referred to hereinafter as ECII) to review findings of the large scale trials and other related biosafety studies on Bt brinjal. Such a Committee got constituted on 29<sup>th</sup> May 2009. One of the terms of reference of ECII was to review the comments from NGOs, national and international experts. The Committee had a tenure of 3 months.</p> <p><a href="http://www.moef.nic.in/divisions/csurv/geac/cons_exp_committee.pdf">http://www.moef.nic.in/divisions/csurv/geac/cons_exp_committee.pdf</a></p> <p>In 2008-09, for at least 7 months or so, GEAC received many representations from India and abroad, based on full data put out here: <a href="http://www.moef.gov.in/sites/default/files/geac/bt_brinjal.html">http://www.moef.gov.in/sites/default/files/geac/bt_brinjal.html</a></p> <p>The 91<sup>st</sup> meeting had decided to create a Sub Committee with representatives from different ministries and institutes, and the ToR decided in the meeting was both review of the adequacy of data, suggestion for further studies if any, and review of representations received by GEAC.</p> <p><a href="http://www.moef.gov.in/sites/default/files/geac/decision-jan-91.pdf">http://www.moef.gov.in/sites/default/files/geac/decision-jan-91.pdf</a></p> <p>The EC2 held its meetings on July 30<sup>th</sup> 2009 and August 31<sup>st</sup> 2009, and its report dated 8<sup>th</sup> October 2009 was placed for GEAC's consideration on 14<sup>th</sup> October 2009.</p> <p><a href="http://www.moef.nic.in/sites/default/files/Report%20on%20Bt%20brinjal_2.pdf">http://www.moef.nic.in/sites/default/files/Report%20on%20Bt%20brinjal_2.pdf</a></p> <p>This report has a clear section which had responses to the representations received from experts and others amongst the public.</p>

	<p>the sub-committee report but also has many other sections written up by someone.</p> <p>The time being given is only 30 days. In the case of Bt brinjal, feedback was sent to GEAC for months, from January 2009 onwards and all of it was taken on board including from a campaign called I Am No Lab Rat.</p> <p>No data has been shared in the public domain so far. This, despite repeated CIC orders and earlier SC &amp; CIC orders.</p>	
After GEAC cleared Bt brinjal on October 14 <sup>th</sup> 2009	???	<p>GEAC left the final decision for approval on the Minister for Environment and Forests given that a GM food crop would be allowed in the country for the very first time if permitted. On October 17<sup>th</sup> 2009, the then Environment Minister announced that he will collect written feedback from the public till December 2009 (2.5 months), after which he also organized a 7-city public consultations tour in which more than 8000 citizens participated directly and got an opportunity to share their analysis, views and concerns. Hundreds of citizens wrote in.</p> <p>The Minister also sought the views of many state governments.</p> <p>The same was compiled in detail by Centre for Environment Education (CEE) and along with this, the Minister announced his decision of an indefinite moratorium on Bt brinjal on February 9<sup>th</sup> 2009.  <a href="http://www.moef.nic.in/downloads/public-information/minister_REPORT.pdf">http://www.moef.nic.in/downloads/public-information/minister_REPORT.pdf</a></p>
		To this day, Bt brinjal has not proven itself safe and made a comeback.