

## **GM Watch: Dr. Bhargava's letter on Bt cotton toxicity**

posted 28 May 2008

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NOTE: The leading Indian scientist P M Bhargavaa, who was nominated by India's Supreme Court to India's apex GM regulatory body, has found that the regulators have ignored evidence of toxicity in Bt cotton.

Below is the letter Dr. Bhargava sent to the director of the Genetic Engineering Approval Committee (GEAC) pointing out that the three documents relied upon by the GEAC 'contradict ... unequivocally' the regulators' claim that the mortality of sheep in Andhra Pradesh, which had fed on Bt cotton. might be due to pesticide residues rather than Bt toxin.

The co-Chair of the GEAC, incidentally, is also a board member of the biotech-industry backed lobby group ISAAA, which has as its goal the promotion of GM crops in developing countries. In fact, the GEAC is awash with such conflicts of interest - see item 2.

For press coverage on Dr. Bhargava's letter see

[http://timesofindia.indiatimes.com/India/Panel\\_ignored\\_Bt\\_cotton\\_toxicity\\_evidence/articleshow/3049910.cms](http://timesofindia.indiatimes.com/India/Panel_ignored_Bt_cotton_toxicity_evidence/articleshow/3049910.cms)

<http://www.ibnlive.com/news/is-india-ready-for-genetically-modified-food/65538-19.html>

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1. Dr. Bhargava's letter to the GEAC

May 14 2008

Dr R Warriar  
Director & Member Secretary GEAC  
Ministry of Environment and Forests  
Paryavaran Bhavan  
CGO Complex, Lodi Road  
New Delhi 110 003

cc: by courier

Dear Dr Warriar,

(1) Thank you very much for your letter no.13/07/2007-CS-II(GEAC) of the 1st May and its enclosures. I am most appreciative of your efficiency and concern.

(2) As regards the three documents you sent to me regarding the mortality of sheep in certain districts of Andhra Pradesh, may I make the following comments:

In item 4.1.6 of the minutes of the 83rd meeting of GEAC held on 2.4.08 you had mentioned: "that the GEAC had given an opportunity to NGOs to present their views/evidence regarding

sheep death in Andhra Pradesh. The matter has also been examined by the State Government and report received from Directorate of Animal Husbandry, Hyderabad, Indian Veterinary Research Institute, Izatnagar, U.P indicate that the sheep deaths might be due to high content of Nitrates/Nitrites, residues of hydrocyanide (HCN) and organophosphates which are common constituents of pesticides used during cotton cultivation and not that of Bt toxin. It was further informed that data on toxicity of Bt protein to higher mammals is extensively available as Bt cotton was released globally about a decade ago. Further, prior to release of Bt cotton in India a battery of studies to assess the safety of Bt toxin to the environment and animals have been conducted." (I had requested for a copy of the minutes of the meeting with the NGOs, which I have not yet received.) The three documents you sent, contradict the above statement unequivocally. For example, the letter from Department of Animal Husbandry, Government of Andhra Pradesh, dated 9th May 2007, says "The gathering observed that the biosafety studies were not taken up in sheep and also trials did not include continuous grazing / feeding of complete Bt cotton plants to animals. It was opined that biosafety studies should be on applied aspects like continuous grazing of animals on harvested or intact Bt cotton plants and the quantitative analysis of Bt protein and Gossypol in different stages i.e. even after harvesting." The above letter also says that, in 2007, the samples were "negative for HCN, Nitrates, Nitrites, Alkaloids and Glycoside". The letter further adds that "the department has issued guidelines to the staff to create awareness among the shepherds and to advise them not to graze their animals in harvested Bt cotton fields till the definite cause is established", to prevent "economic loss to farmers" that occurred in 2007, apparently on account of Bt cotton. The Joint Director of IVRI, Izatnagar, also says in his letter of 18th June 2007 to you, "Bt Cotton samples tested in the Toxicology Laboratory of this Centre, showed absence of HCN, Nitrate/Nitrite, Alkaloids and Glycosides". In the third letter you sent, the Associate Dean of S V University says, "The biosafety studies on grazing Bt cotton crop by sheep are lacking". In fact, the three letters taken together, strongly suggest the possibility (even the probability) of the death of sheep being due to Bt cotton. They also underscore the fact that no serious studies to rule this out have been done so far. This would be a major argument to suspend all cultivation of Bt Cotton until we have definitive data on the toxicity of Bt plants to animals on field. Incidentally, contrary to what has been stated in the minutes of the 83rd meeting, HCN is not a "common constituent" of any pesticide.

(3) As regards the document, "Assessment of in vitro digestibility of CP4EPSPS (protein)", firstly the study has been done by Monsanto/Mahyco which is an interested party. It has not been confirmed by any independent investigation. In fact, in footnote 2, it is stated that "this article must, therefore, be hereby marked "advertisement". I have also noted that there was a nine-and-a-half months delay between submission of the manuscript and its acceptance by Journal of Nutrition which is one of the best-known journals in the field. This clearly indicates that there were, perhaps, notable comments from the referees. The document, therefore, has no value. I am also intrigued by the fact that this paper which is in public domain has been marked "confidential".

(4) As regards the document you sent on "Bioinformatics evaluation of CP4EPSPS protein", the main technical problem with the study is that there could have been other changes in the protein make-up of the organism after genetic engineering, generating new allergens! This can only be found out by proteomics analysis and cataloguing of all qualitative changes in the protein profile after genetic engineering of the organism. It is also noteworthy that, according to Monsanto's own statement, "This project does not meet the US EPA Good Laboratory Practice requirements". Further, it is stated very clearly by Monsanto that "no claim of confidentiality is made for any information contained in this study". Why is it then

marked confidential? It is also not clear whether the investigators ensured that the sequence of the protein as produced in the plant, was identical with the sequence of the normal protein. What has been studied is the normal protein.

(5) As regards the detailed information you sent on "Acute oral toxicity study in albino mice" of the CP4EPSPS protein used to confer resistance to weedicide glyphosate, again the entire study has been done by Monsanto/Mahyco and has not been confirmed by anyone else. The samples were not even double blinded. Indeed, how do we know that both the experimental and the control groups did not receive just a placebo. Further, only acute toxicity has been looked at. What about chronic toxicity, as in the case of aflatoxin or many carcinogens? In view of these lacunae, the study is of no value and as good as not having been done.

(6) As regards the report you sent on "Bollgard II Roundup Ready Flex Cotton", the pollen flow studies, the seed germination study, and the soil microbial studies have all been done by Monsanto/Mahyco and not confirmed by anyone else. The pollen flow studies actually show pollen flow upto 10 metres. This means that in a two hectare farm, approximately one-third of the land will not be available for plantation. We should remind ourselves that in our country, small and marginal farmers with holdings of two to four hectares and less than two hectares, respectively, represent 84 percent of our farming community. This alone, even on the basis of unconfirmed studies of Mahyco on pollen flow should rule out the use of Bt cotton by small and marginal farmers. In the soil microbial studies, even if we assume that they are reliable (for which there is no evidence whatsoever), it is not enough to have the total number of organisms determined. What about the bacterial profile which is far more important? What about the effect on soil micronutrients? Further, on page 2 of the Executive Summary, it is mentioned that the Bt cotton hybrids under trial have potential for higher seed cotton yield in comparison to the conventional (non-Bt) hybrids. This is surely a misleading statement, for it is not the production that may be affected by the Bt-gene but the destruction by pests.

I have been appreciative of your putting the minutes of the GEAC meeting on your website and thus in public domain. It would, therefore, be fair to put the comments you receive on the minutes or on matters arising out of minutes, also in the public domain. The above comments may also be kindly circulated to GEAC members and put up for discussion at the 28th May meeting of the GEAC.

With warm personal regards,  
Yours sincerely,  
(P M Bhargava)

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2.GEAC's poor record of regulation  
Bhaskar Goswami  
India Together, 16 August 2007  
<http://www.indiatogether.org/2007/aug/agr-geac.htm>

[EXTRACT ONLY]

The Genetic Engineering Approval Committee, says Bhaskar Goswami, itself needs to be regulated to ensure it plays a balanced role.

Many GEAC members, who are expected to take objective decisions, are themselves developers of GM crops and members of bodies sponsored by the biotech industry. A media advisory from the Centre for Sustainable Agriculture earlier this year noted many conflicts of interest.

Dr. C D Mayee, co-Chair of the GEAC and the DBT nominee, is also a Board member of ISAAA an international network funded by biotech majors such as Monsanto, Bayer and Dupont. Dr T V Ramanaiah, Ex-Member-Secretary, Review Committee on Genetic Manipulation, had personally approved hundreds of GM crop field trials that have happened in India so far. He has quit his post in the DBT and has joined Pioneer HiBred International as their Biotech Regulatory Affairs Manager.

Dr Deepak Penthal (University of Delhi), Dr Akhilesh Tyagi (UD-South Campus), Dr B M Khadi (CICR), Dr P Anand Kumar (National Research Centre of Plant Biotechnology) and Dr Rakesh Tuli (National Botanical Research Institute) were others identified as holding (or having held) regulatory roles despite a personal interest in the development of GM varieties.