

**Minutes of the first meeting of the Sub-Committee on Bt Cotton and related issues held on 10<sup>th</sup> May 2006.**

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The first meeting of the Sub-Committee on Bt. Cotton and related issues was held on 10th May 2006 under the Chairmanship of Dr C D Mayee Chairman ASRB, and Co-Chair GEAC at in the Committee Room, NRC on Plant Biotechnology, IARI, Pusa, New Delhi.

List of participants is annexed.

1.0 At the outset, the Chairman welcomed the members and thanked MoEF for taking the initiative of addressing a long-standing issue with respect to streamlining the regulatory approval processes for transgenic crops. In his opening statement he reflected on the significant changes in the cotton cultivation scenario both globally and in the country after the introduction of Bt technology. India has approved the cultivation of Bt cotton with cry 1 Ac (Mon 531 event) in 2002 after extensive and exhaustive biosafety and agronomic evaluation. Within a period of four years more than 40 hybrids have been released by the GEAC. Experience has confirmed the efficacy of the Bt technology for control of bollworm. The technology in no way increases the yield potential of a hybrid but because of the inherent protection to bollworms there is a saving of bolls, which results in increase in yield. Therefore yield alone cannot be the criteria for deciding the performance of a hybrid. It was suggested that parameters such as level of protein expression, staple length, susceptibility to diseases, etc should also be taken into consideration while selecting promising hybrids as these parameters also contribute to the economic gain.

2.0 He initiated the meeting by inviting Dr. Ranjini Warriar, Additional Director and Member Secretary GEAC to brief the Committee on the genesis of the sub-Committee. She informed the Committee on the various policy decision taken by the GEAC since 2002 and the feed back received from various expert groups, seed companies, State Govt and NGOs which necessitates reconsideration of various issues based on the experience gained during the last four to five years. It is in this context, a decision was taken to set up a sub-Committee mainly with a view to streamline the approval process to make it effective and practical.

3.0 The Committee briefly discussed the TOR and it was agreed that issues relating to the Bt cotton approval process may be taken up first and accordingly it was agreed to consider TOR a, b and d. The TOR on other aspects would be deliberated by the sub-Committee in its subsequent meetings.

4.0 The Chairman then invited the Expert Members to present their views. There was a general consensus that extensive biosafety and agronomic testing

is not necessary for approved gene/events. Some Members suggested that one crop season of multi-locational testing in tandem with ICAR /SAU trials is adequate. If the hybrid consistently performs better than the Bt check the genotype merits consideration for commercial release. Director, CICR, Nagpur, representing ICAR stated that the norms applied by ICAR in case of non-transgenic crops under AICCIP trials should be applicable to Bt cotton hybrids also so that the best performing hybrids can be offered to the farmers. In response, views were expressed that ICAR system is not mandatory for non-Bt hybrids and registration with ICAR is voluntary. Besides ICAR within the available infrastructure is able to test only a limited number of hybrids. Therefore once the gene/event has been tested for its biosafety it should be treated on par with the non-Bt hybrids. Views were also expressed that due consideration for the agronomic value of the hybrid should be given and not completely done away with while conducting multi-location trials.

5.0 After detailed deliberation it was agreed, since Bt technology is introduced specifically to control bollworms the parameters of prime importance are (i) confirmation of the gene/event, (ii) level of protein expression and (iii) morphological equivalence to its non – Bt counterpart wherever it is available.

6.0 The Committee then invited the Seed Industry Association to present their views on streamlining the regulatory system /approval process for Bt Cotton. The committee noted the following suggestions made by the Seed Industry Association.

a. A move towards an “event based approval system” instead of the case by case approval process presently adopted by the GEAC under Rules 1989, would speed up the introduction of new and diverse products for the Indian farmer, stimulate competition and offer a wider choice, without compromising bio-safety and environmental safety. Since bio-safety, environmental safety and economic advantage efficacy of *Cry 1 AC* gene (Mon 531 event) has been already established, selling of new Bt cotton hybrids containing approved events viz., *Cry 1 AC Mon 531*, could follow the provisions of Seed Act, 1966 after registration with GEAC. The registration with GEAC could be based on the data submitted by the Companies to the RCGM. RCGM would verify the technical data on gene equivalence, morphological description, effectiveness of the gene/product and source of the technology submitted by the Company. It was further stated that once an event is approved in a crop species for bio-safety and environmental safety the commercialization of that event in different genetic backgrounds of the same crop does not require any further regulatory testing in other developed countries like U S A.

b. Under the Seed Act, 1966, testing by ICAR is not mandatory for sale /commercialization of any hybrids /varieties. Therefore, this should not be made mandatory for transgenic crops.

c. The seed marketing is governed by the provisions of the Seed Act, 1966 and Seed Control Order, 1983. In case of any loss to the farmers, their interests are adequately protected by the Consumer Protection Act, 1986. The Bt cotton hybrid seed falls under the purview of the above mentioned two Acts.

d. To comply with the GEAC conditions the Seed Industry is willing to adopt a three tier "self regulation of GM crops" namely at the pre-registration, registration and post-registration phase. The procedure for self-regulation during the various stages of registration was also presented.

7.0 During the deliberations, views were expressed by some Members that there is a need to develop a mechanism for event confirmation and expression studies in addition to strengthening the enforcement mechanism. The representative of Seed Industry Association clarified that event confirmation is being currently tested through event specific primers provided by the technology provider. Views were also expressed that, to avoid a conflict of interest the monitoring and evaluation mechanism should be entrusted to an independent agency.

8.0 After detailed deliberation the Committee made the following recommendations:

**A. Measures to streamline the evaluation of Bt cotton hybrids under RCGM/GEAC/ICAR systems and seed production for transgenic cotton in CVRC notified and un-notified varieties in released gene /event.**

**a. Recommendations for Cry 1 Ac gene (Mon 531 EVENT)**

i. New Bt cotton hybrids containing the cry 1 Ac gene (Mon 531 event), can be permitted for controlled multi-locational trials (MLT) by RCGM based on the following data:

- Confirmation of gene event through DNA fingerprinting
- Level of Protein expression.
- Morphological equivalence through DUS.
- Bio-efficacy data generated at lab and green house conditions.

ii The protein expression and gene equivalence data submitted from a standard laboratory like CICR, Nagpur, NRC for Plant Biotechnology, New Delhi, University of Agriculture, Bangalore, NBPGR, New Delhi, NRCD, New Delhi, TERI, New Delhi may be accepted.

iii. Along with MLT, a minimum of two location trials should be conducted at each State Agriculture University (SAU) per hybrid per zone for assessing the suitability of the hybrid for a specific agro-climatic zone and evaluating the agronomic benefit of the hybrid.

iv. In Central and South zone, the data generated from MLT/SAU will be 50 % under rain fed conditions and 50% under irrigated/semi-irrigated conditions.

v. The data from the MLT and SAU trials would be evaluated by the Monitoring – cum –Evaluation Committee (MEC) and the recommendations submitted to the GEAC by the RCGM.

vi. The GEAC may consider the recommendations of RCGM/MEC for the purpose of environmental release as per the provisions of Rules 1989 of EPA.

vii. After approval for environmental release, by the GEAC, it may be voluntary on the part of the applicant to go for testing under the AICCIP trials to qualify under the ICAR system.

viii. Responsibility of monitoring MLTs should be entrusted to SAUs. The sub-committee endorsed proposal on Alternate Monitoring Mechanism proposed by DBT and was of the view that the new mechanism should be enforced in a timely manner during the current crop season. The cost of monitoring would be borne by the Applicant. The fee of Rs. 5000/- per hybrid in MLT trials would be deposited with the Controller of the University who in turn will make available to the Monitoring Team the expenses for organizing and conducting the monitoring and report preparation as per the prescribed norms. If there are any LSTs conducted in the jurisdiction of a SAU, Rs. 500/- per hybrid would be deposited by the applicant with the University for monitoring.

ix. The seed production in an area of 100 ha may be permitted by RCGM along with the MLT and SAU trials.

x. Under the proposed new system, there is no need to differentiate between notified and non-notified varieties.

xi. The new system would be applicable to all GEAC released new gene/event once it has been tested for a period of three years and the GEAC clearance has been renewed for the same.

**B. To recommend the period of Large Scale and ICAR Trials and seed production for new gene in cotton crop/new crops.**

i. In respect of new Bt cotton hybrids containing new gene/event the current approval system in practice would apply.

ii. The protocol for biosafety data generation during –field trials would require appropriate modification on a case to case basis.

iii. During the deliberations it was informed that there have been representations for seeking clarification on the protocol for LST recommended by the Nagarajan Committee. The Committee requested the Chairman to examine the protocol and suggest changes if any.

iv. For verification of the gene/event and protein expression, the following data from any standard laboratory as mention in para A(a) (ii) should be submitted by the Company to RCGM:

- Confirmation of gene event through DNA fingerprinting
- Level of Protein expression.
- Morphological equivalence through DUS.
- Bio-efficacy data generated at lab and green house conditions.

v. The part of the sample submitted for toxicological study should be forwarded to the laboratory for gene/event /protein expression verification for which necessary instruction may be issued by the GEAC.

**C. Permission for LST/Commercial release based on agro-climatic conditions rather than the zonal concept of Central/ South / North zone based on political boundaries recommended by ICAR:**

The Member Secretary GEAC, informed the Committee that the GEAC as received representations from some of the industry to permit LST/commercial release based on the concept of agro-climatic suitability instead of state / zone wise approval.

After a brief discussion the Committee opined that the present zonal system envisaged by the ICAR is based on several factors such as cotton cultivation practices, agr-climatic factors and administrative requirement under the Seed Act/Order. Accordingly the SAU jurisdiction in each state has been defined. Therefore the Committee concluded that the matter needs a critical look before any changes are suggested. The Committee suggested that the GEAC may request ICAR to examine the above issue and redefine the zonal concept if necessary.

9.0 Before concluding the meeting, it was informed by the Member Secretary that GEAC has accorded approval for several Bt cotton hybrids during the last two meetings based on certain criteria. Therefore the Committee was requested to indicate the applicability of the new procedure. It was agreed that the new recommendations would be applicable in prospect that is during the next crop season and not ~~retrospect~~ from current season.

10.0 It was also decided that representatives of some of the State Dept of Agriculture may be invited for the next meetings of sub-committee.

The meeting ended with a vote of thanks to the Chair.

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**List of the Participants who attended the First Meeting of the Sub-Committee on Bt Cotton and Related Issues held on 10.5.2006 in the Ministry of Environment & Forests, New Delhi.**

<b>S. No.</b>	<b>Name of the participants</b>
1.	C.D. Mayee, Chairman
2.	Dr M. Uday Kumar, Deptt of Crop Physiology
3.	B.M. Khadi, CICR Nagpur
4.	Dr. P Anand Kumar, Scientist, NRCPB, IARI Campus Pusa
5.	T.V. Ramaniah, Director, DBT & Member Secretary GEAC
6.	A.K. Tyagi, Professor, Delhi University (South Campus)
7.	Dr. R. Warriar, Additional Director & Member Secretary GEAC