

REPORT

of the

**SUB-COMMITTEE ON BT COTTON AND RELATED ISSUES
(Recommendations for Streamlining the Current Regulatory Framework for
Transgenic Crops)**

**MINISTRY OF ENVIRONMENT & FORESTS
GOVERNMENT OF INDIA**

JUNE 2006

1.0 Preamble:

1.1 The Ministry of Environment & Forests, Government of India, vide their OM No. 10/13/2005–CS – GEAC dated 28.4.2006 constituted a sub-Committee under the Chairmanship of Dr C D Mayee, Chairman ASRB, and Co-Chair GEAC, to look into the existing processes, protocols and other related issues and give recommendation for rationalization of the same.

1.2 The Committee consisted of the following members:-

- a) Dr C D Mayee, Chairman ASRB, and Co-Chair GEAC, **Chairman**
- b) Dr Akhilesh Tyagi, Professor, Centre for Plant Genomics & Department of Plant Molecular Biology, University of Delhi. South Campus, New Delhi. **Member**
- c) Dr M. Udaya Kumar, Deptt of Crop Physiology, University of Agricultural Science, Hebbal, GKVK, Bangalore. **Member**
- d) Dr P Anand Kumar, Principal Scientist, National Research Centre on Plant Biotechnology, (NRCPB), IARI, New Delhi-110012. **Member**
- e) Dr. B. M. Khadi, Director, Central Institute for Cotton Research, Nagpur. **Member**
- f) Dr T V Ramanaiah, Director, DBT, New Delhi. **Member**
- g) Dr R Warriar, Additional Director, MoEF. **Member Secretary**
- h) Representatives of SAUs and SDAs (**Co-opted**).
- i) Dr O. P. Govila, Retired Scientist, Department of Genetics, IARI, New Delhi (**Co-opted Member**)

1.3 The terms of reference of the sub-Committee are given below:-

- a) To recommend measures to streamline the evaluation of Bt cotton hybrids under RCGM/GEAC/ICAR systems and seed production for transgenic cotton in CVRC notified and non-notified varieties in both released gene/event and new gene/event.

- b) To recommend the period of Large Scale and ICAR Trials and seed production for new genes in new crops.
- c) Mechanism to monitor the performance of Bt cotton.
- d) Recommendations to implement the Alternate Monitoring Mechanism.
- e) Review of GEAC compliance conditions in respect of refugia, IRM practice, IPM strategy, appropriate packaging practice etc.
- f) Parameters and benchmarks for deciding the superiority of the hybrids evaluated under RCGM / ICAR system.
- g) Any other recommendation on related aspects.

1.4 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 in the Committee Room, NRC on Plant Biotechnology, IARI, Pusa, New Delhi. 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 TOR on other aspects would be deliberated by the sub-Committee in its subsequent meetings. Minutes of the first meeting are annexed to this report (Annexure-1).

1.5 The interim recommendations that emerged from the deliberations of the first sub-Committee meeting were discussed in the meeting of the GEAC held on 22.5.2006 wherein the GEAC accepted 'in principle' the interim recommendation of the sub-Committee on the proposed regulatory framework for *cry1Ac* gene (Mon 531 event). However in view of the reservations expressed by the representative of ICAR, the GEAC requested the Committee to look into the views expressed by ICAR. The GEAC further advised that some fine tuning of the recommendations made in respect of SAU trials is required for which the sub-Committee may consult the SAUs. The issue of applicability of the new procedure was also discussed. It was agreed that the recommendations would be applicable prospectively. The Committee requested the sub-Committee to consider the implications of the new procedure and recommend a cut off date from which the new procedure would apply. The GEAC also requested the sub-Committee to indicate a benchmark for evaluating the superiority of the hybrid based on fibre length and quality.

1.6 The second meeting of the sub-Committee was held on 8.6.2006 to discuss and finalize the recommendation in respect of the mandate given by MoEF and GEAC.

1.7 The report has been finalized through a consultative process. In the first meeting of the sub-Committee, the representatives of the industry association were invited to present their views on streamlining the regulatory system /approval process for Bt Cotton. The representatives of State Agriculture Universities (SAUs) attended the second meeting of the sub-Committee from the nine cotton-growing states. The Committee also considered and took on board the representations received from several NGOs regarding the irregularities during field trials.

2.0 Analysis of the Constraints in the Current Regulatory Framework:

2.1 With the introduction of Bt technology, there has been a significant change in the cotton cultivation scenario both globally and in the country. India has approved the cultivation of Bt cotton with *cry1Ac* (Mon 531 event) in 2002 after extensive and exhaustive biosafety and agronomic evaluation. Within a period of four years about 58 hybrids have been released by the GEAC and about 121 Bt cotton hybrids are under various stages of field trials. The area under Bt cotton in India has increased from 72,682 acres in 2002 to 31,00,000 acres in 2005. This area is expected to increase substantially over 50 lakh acres during 2006. In addition to Bt hybrids containing the *cry1Ac* gene (MON 531 event), which was earlier approved by the GEAC and is in commercial cultivation since 2002, the GEAC approved hybrids with three new gene/event namely Bt hybrids expressing fusion genes (*cry 1Ab+cry1Ac*) ‘GFM *cry1A*’ developed by M/s Nath Seeds, Bt hybrids expressing *cry1Ac* gene (Event-1) by M/s JK Seeds Ltd and Bt hybrids expressing stacked genes *cry1 Ac* and *cry2Ab* (MON 15985 event)—BG-II by M/s Mahyco.

2.2 As per the current practice, the GEAC is following a case-by-case approval, which mandates extensive testing of each hybrid under RCGM/GEAC/ICAR trials

even if the hybrid contains a gene/event cleared from biosafety angle. Conduct of multi-location/ replicated field trials is being approved by the RCGM. The minimum number of trials to be conducted per zone is 5 locations in north, 8 locations in central and 6 locations in south zones. In each state falling under any of the zones, a minimum of one trial and maximum of 4 trials need to be conducted by the applicant. This is followed by large scale testing under GEAC in farmer's field where the applicant needs to conduct field trials in a minimum of 80 locations per zone per hybrid. The cotton cultivation is divided into 3 zones i.e. north, central and south zones. North zone consists of three states i.e. Punjab, Haryana and Rajasthan; Central zone consist of Gujarat, MP and Maharashtra and South zone consist of A.P., Karnataka and Tamil Nadu. If a single hybrid (cotton) is tested in all zones, the total number of trials would be 240 and for two zones it will be 160 and accordingly 80 for single zone. Currently, large number of companies is in the fray with multiple entries per company to cater several niche markets, which makes the number of trials in a zone too large. The field trials are monitored by MEC, a central Committee constituted by RCGM. In view of the large number of entries and trials, MEC and ICAR have been facing logistic and infrastructural problems of handling and monitoring. Considering the changed scenario, it was felt that there is a need for an alternate monitoring mechanism involving the SAUs, which have a better access to regional monitoring.

2.3 Experience and high adoption of Bt cotton by farmers have confirmed the efficacy of Bt technology for control of bollworms. It is also a well known fact that 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, and also reduction in number of sprays drastically, which results in increase in yield. However, the decision for commercial release of a Bt cotton hybrid is largely guided by the yield advantage evaluated under the ICAR trials. Parameters such as level of protein expression, susceptibility to diseases, staple length, staple strength, etc need to be given due consideration while selecting promising hybrids as these parameters also contribute to the economic gain.

2.4 While the farmers associations and the State Governments have been requesting for release of high yielding Bt cotton hybrids at an affordable price, the NGOs have reported poor performance, adverse impact on cattle health and irregularities during field trials.

2.5 As part of the IPM strategy, the GEAC has stipulated planting of a refugia of the same non Bt cotton hybrid at the periphery of the Bt cotton field equivalent to five rows or 20% of total sown area which ever is more. This requirement is not being complied by sizable number of farmers. With the increase in acreage under Bt cotton the early development of insect resistance to Bt gene in the near future is an area of concern, which we need to address. The matter has been further complicated due to rampant sale of spurious / illegal Bt cotton seeds.

2.6 While GEAC has made considerable efforts to streamline the existing mechanism, the issues involved are complex. In light of the experience gained during the last four to five years there is an urgent need to revisit the existing policies for evaluating the performance of transgenic crops.

2.7 Based on the above analysis, the Committee is of the view:

a. Extensive biosafety and agronomic testing is not necessary for approved gene/event. Once the gene/event has been tested for its biosafety it should be treated on par with the non-Bt hybrids.

b. 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.

c. While due consideration for the agronomic value of the hybrid should be given and not completely done away with, the parameters of prime importance to assess the efficacy of Bt technology include (i) confirmation of the gene/event, (ii) level of

protein expression and (iii) morphological characterization based on DUS parameters.

d. 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 carrying an approved event which has been declared bio-safe and being cultivated extensively.

e. Since agriculture is a State subject involvement of the SAUs and State Agriculture Departments is essential as they have elaborate establishment in place to monitor the performance of the agricultural crops in their jurisdiction.

f. To address the concerns expressed by the NGOS, there is an urgent need to strengthen the enforcement mechanism, disseminate of information regarding the field trials and enhance the awareness and extension work at the field level.

2.8 The recommendations of the Sub-Committee in respect of the TOR assigned to the Committee are enumerated in the subsequent section on the basis of the above analysis.

3.0 Recommendations of the Sub-Committee:

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 *cry1Ac* gene (Mon 531 EVENT)

The global area of transgenic Bt crop cultivation is approximately 26.3 million ha. The transformation event MON 531 present in the Bollgard genotypes is the major event in global Bt cotton. India has approved the commercial release of this event in 2002 after extensive biosafety assessment. In view of the considerations such as: i) about

58 Bt cotton hybrids containing this event are already under commercial cultivation, ii) GEAC has renewed its approval for the first three Bt cotton hybrids and iii) the need for more diverse and niche-based hybrids, the Committee felt that case by case approval and extensive field testing are not necessary for Bt Cotton hybrids expressing MON 531 event. The Committee recommends an 'event based approval system as follows:

i. New Bt cotton hybrids containing the *cry1Ac* gene (Mon 531 event), can be permitted for controlled multi-location trials (MLT) by RCGM based on the following data:

- Confirmation of gene event through molecular characterization.
- Level of Protein expression in greenhouse/station strip trials
- Morphological characterization using DUS descriptors
- Bio-efficacy data generated in laboratory conditions.
- Authorization/NOC from the technology provider to use the technology in case of sub licensee

ii The protein expression and gene equivalence data submitted from a standard laboratory like CICR, Nagpur, NRC for Plant Biotechnology, New Delhi, University of Agricultural Sciences, Bangalore, NBPGR, New Delhi, NRCDFP, New Delhi, TERI, New Delhi may be accepted, if the infrastructure and protocols are available in the institutions. In case any IP issues regarding protocols are involved the data from the technology provider may be accepted. A uniform standard protocol is desirable in order to avoid variation in laboratory conditions.

iii. The protocol for MLT as presently recommended by RCGM (Annexure –II) may be adopted.

iv. Along with MLT, minimum of three location trials falling under different universities spread over the zone is suggested to assess the suitability of the hybrid for a specific agro-climatic zone and evaluate the agronomic benefit of the hybrid.

The testing procedure under SAU trials is annexed to this report as Annexure –III. Testing Protocol should be the same in all three zones.

v. In Central and South zones, the data may be generated from rain-fed (50%) and irrigated (50%) conditions under MLT, and at least one SAU location trial per zone under rain-fed conditions.

vi. 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.

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

viii. 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 like any other non-Bt hybrid or variety.

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

b. Recommendations for Bt cotton hybrids approved by the GEAC for commercial release during Kharif 2006.

The GEAC has accorded conditional approval to Bt cotton hybrids expressing three new genes/events namely Bt hybrids expressing encoding fusion genes (*cry1Ab+cry1Ac*) 'GFM *cry1A*' developed by M/s Nath Seeds, Bt hybrids expressing *cry1Ac* gene (Event-1) by M/s JK Seeds Ltd and Bt hybrids expressing stacked genes *cry1Ac* and *cry2Ab* (MON 15985 event)—BG-II by M/s Mahyco for a period of three years as per the provision of Rules 1989.

In respect of the above scenario, the current approval system as outlined in Annexure-IV would apply. The Protocol for large-scale trials specifying the number of locations and parameters to be monitored is annexed to this report as Annexure-V.

The new system / procedure outlined in para A (a) would be applicable to all GEAC released new genes/events once they have 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 gene in cotton crop/new crop**, the current approval system as outlined in Annexure-IV would apply.

ii. In respect of Bt cotton containing a new gene/event, the Protocol for MLT/LST as annexed at Annexure II and IV would apply.

iii. The protocol for biosafety data generation during-field trials would require appropriate modification on a case-to-case basis in respect of new crops.

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

- Confirmation of gene event through molecular characterization.
- Level of Protein expression.
- Morphological characterization based on DUS parameters.
- Bio-efficacy data generated in laboratory conditions.
- Authorization/NOC from the technology provider to use the technology in case of sub licensee

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. Mechanism to monitor the performance of transgene and Recommendations to implement the Alternate Monitoring Mechanism

a. Pre- Release Monitoring:

i. Responsibility of monitoring Multi-location field trials (MLT) and Large –Scale field trials (LST) should be entrusted to the State Agriculture Universities (SAU) under the direct supervision of Director Research of each SAU. The sub-committee endorsed the proposal on Alternate Monitoring Mechanism proposed by DBT and is of the view that the new mechanism should be enforced in a timely manner during the current crop season.

ii. The Composition of the Monitoring Team shall consist of:

- | | | | |
|----|---|---|-------------|
| 1) | Director of Research, Nodal person
State Agriculture University | - | Team Leader |
| 2) | Plant Breeder (concerned crop)
State Agriculture University | - | Member |
| 3) | Entomologist- Head of the Department
or Nominee State Agriculture University | - | Member |
| 4) | Agronomist- Head of the Department
or Nominee State Agriculture University | - | Member |
| 5) | Pathologist- Head of the Department
or Nominee State Agriculture University | - | Member |

- | | | | |
|-----|---|---|--------|
| 6) | Subject matter specialist
Relevant to the transgene (Biotechnologist). | - | Member |
| 7) | Joint Director/ Deputy Director, Agriculture
State Government | - | Member |
| 8) | Agriculture Officer of the concerned district
State Government | - | Member |
| 9) | Nominee of RCGM | - | Member |
| 10) | Nominee of GEAC | - | Member |

Director of Research of each SAU may be advised to constitute a Monitoring Team as per the composition given above. It is possible that there may not be any trial locations in some of the SAU's jurisdiction and in that case, the Monitoring Team will not over see any trial and wait for the next season when such trials may take place.

The Director of Research may include additional members or drop not relevant Members based on transgenic crop and the trait.

iii. The Terms and conditions of the Monitoring Team as outlined below may be considered:

1. The Nodal person as identified, would be responsible for monitoring of transgenic cotton/ and other field trials conducted in the jurisdiction of State Agriculture University by constituting Monitoring Teams as per the composition given above. The Nodal person shall also be responsible for maintenance of grants received from the Government of India/ fees collected from the applicants for this purpose.

2. The Monitoring Team(s) shall visit the fields for minimum of two times during the cotton crop season matching boll development and other important stages of the cotton crops. All the replicated field trials being conducted by the applicants in its SAU's jurisdiction and at least 25% of large-scale field trials in its jurisdiction would be monitored. The Monitoring Teams to observe the conduct of large scale and replicated field trials laid out by the applicants on transgenic cotton or other crops as per the conditions given in the experimental trial permits issued by the DBT/ MoE&F.
3. The Monitoring Team(s) shall also observe and advise on collection of data by the applicants on the objectives of large scale and replicated field trials on transgenic crop as mentioned above.
4. The Monitoring Team(s) may advise minor modifications in the collection of data based on the nature of gene expression in transgene and prevailing situation at the site of experimentation.
5. The Monitoring Team(s) shall collect the data during its visit and a copy of the data sheet shall be handed over to the applicant for their records along with suggestions if any, for improvement on the conduct of the trial.
6. The Team Leader shall submit the Monitoring Team(s) report on the large-scale field trials to MEC/GEAC and replicated multi-location field trials to RCGM/ MEC within 15 days from conclusion of the last visit. The Director of Research shall maintain the records of monitoring which may be called for by the GOI, if required.
7. The Monitoring Team(s) shall maintain all the information provided by the applicant and/or collected by the Team as confidential.
9. The members of the Monitoring Team(s) shall be entitled TA/DA as per the State Agriculture University norms/ State Government's rules & regulations. TA/DA shall be disbursed to the Members by the SAU.

b. Post - Release Monitoring:

i. Responsibility of post release monitoring should be entrusted to the State Agriculture Universities (SAU) under the direct supervision of Director of Agriculture Extension of each SAU.

ii. The Composition of the Monitoring Team shall consist of:

- | | | | |
|----|---|---|-------------|
| 1) | Director – Extension, Nodal person
State Agriculture University | - | Team Leader |
| 2) | Plant Breeder (concerned crop)
State Agriculture University | - | Member |
| 3) | Entomologist- Head of the Department
or Nominee State Agriculture University | - | Member |
| 4) | Agronomist- Head of the Department
or Nominee State Agriculture University | - | Member |
| 5) | Pathologist- Head of the Department
or Nominee State Agriculture University | - | Member |
| 6) | Subject matter specialist relevant to
transgene (Biotechnologist) | - | Member |
| 7) | Biostatistician | - | Member |

iii. The Terms and conditions of the Monitoring Team as outlined below may be considered:

1. The Nodal person as identified would be responsible for post –release monitoring of transgenic cotton in the jurisdiction of State Agriculture University by constituting Monitoring Team(s) as per the composition given above. The monitoring should be carried out through a scientifically designed survey.
2. The Nodal person shall also be responsible for maintenance of grants received from the Government of India/ fees collected from the applicants for this purpose.
3. The Monitoring Team(s) shall visit the fields for minimum of two times during the cotton crop season matching boll development and other important stages of the cotton crop. The Monitoring Team will record the following information:
 - Date of sowing
 - Seed Rate
 - Method of Planting
 - Spacing
 - Fertilizer Application
 - Micro-nutrient application
 - Irrigation if any
 - Control of pest/disease measures undertaken
 - IPM practices followed
 - Method of harvesting
 - Performance of the hybrid
 - Economic benefits
 - Views of public acceptability / other comments
 - Compliance of GEAC conditions.
 - Any other parameter of relevance

3. The Monitoring team may also be the focal point for providing feed back on the representations received by the GEAC/RCGM through an on the spot verification. Based on the feed back received from the Monitoring Team(s), the MoEF/DBT may make public the facts of the case through a press release/ website.

c. Financial Support:

1. The cost of pre-release monitoring would be borne by the Applicant. The fee of Rs. 5000/- per trial (per hybrid/location) under monitoring in MLT would be deposited with the Registrar/Comptroller of the University who in turn will make available funds to the Director of Research to meet 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/per location would be deposited by the applicant with the University for monitoring.

2. The amount kept in a separate account would be used for the monitoring of the trials, travel, secretarial assistance, stationary, telecommunications, etc. The GOI may provide a special grant in the event of the fee-generated falls short of the actual expenditure involved in conduct and monitoring of the various trials.

Further there is also a need to strengthen the functioning of the regulatory bodies. The Committee recommends the creation of a "Biosafety Fund", the details of whose operation may be worked out.

D) Review of GEAC compliance conditions in respect of refugia, IRM practice, IPM strategy, appropriate packaging practice etc.

a. Refugia/ IRM strategy

1. Though refugia are necessary for IRM, farmers are not growing refugia because of small land holdings and economic considerations. Some of the alternatives to refugia that have been suggested include use of trap crops such as

Bhendi, mestha, cowpea etc. and smaller refuge area comprising of 5% of the total sown area or just a single row.

2. The Committee recommends that before taking a final view on the matter, it is advisable that studies on alternate IRM strategies be conducted with the help of SAU Punjab, CICR, Nagpur and SAU Dharwad for which RCGM may formulate different study modules.

3. The committee recommends that non-bt cotton refugia seeds need not be of the same hybrid of bt cotton. Non-Bt seeds of popular Cotton hybrids can be used as refugia.

b. Alternative IPM strategies

1. There is an urgent need to develop appropriate package of practices for each Bt cotton hybrid keeping in view agro climatic conditions (rainfed/irrigated) of the States/regions by the company selling that hybrid or by the state agricultural universities with funding from that company.

2. The IPM practices being followed in different states should be properly documented by the respective SAUs and awareness regarding the same should be created at all the levels of stakeholders. The need for supply of higher quantity of Bt seeds in each packet supplied by the companies also needs to be examined by the SAUs in light of the germination rate which varies due to variable agro-climatic (rainfed/irrigated) conditions

E) Parameters and benchmark for deciding the superiority of the hybrids evaluated under MEC / SAU / ICAR system.

1. Since Bt 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, it is recommended that the yield should not

be the main criterion for assessing the superiority of the hybrid. However the yield comparison should be with a recently released and related Bt check.

2. The candidate hybrid(s) may be compared with the released non-Bt hybrid check of respective group viz., early / medium / late. The candidate checks may be decided from time to time.
3. For judging fiber quality of a hybrid, the following CIRCOT guidelines/norms should be followed:

Staple class	Length (mm)	Mill requirement %
Short	<20	7
Medium	20.5 – 25.5	36
Medium long	26 -27.5	20
Long	28 – 33.5	32
Extra long	> 34	5

The inherent staple strength of India cotton *hirsutum* germplasm is low and ranges between 19 to 23 g/tex (ICC mode) under rain-fed and irrigated conditions. As 80% of the Indian cotton is grown under rain-fed conditions, it is very difficult to achieve a higher staple strength in HxH hybrids. Hence, an average of 0.75 S/L ratios may be used as benchmark to evaluate the fiber quality of an HxH hybrid.

F) Any other recommendation on related aspects.

a. Applicability of the New procedure.

1. The new recommendations would be applicable from the next crop season. However, to ensure that the seed industry is benefited by the new procedure, there is a need to synchronize the material currently under testing.

2. The GEAC may also issue necessary direction to SAUs regarding the new procedure. While issuing the direction, it may also be emphasized that SAU trials may be taken up only for those events, which have been approved for commercial release after biosafety clearance and recommended by RCGM/GEAC for MLT. As per the requirement of Rules 1989, each SAU is also required to constitute an IBSC before taking up any activity related to transgenic crops.

b. Strengthening the Enforcement mechanism to address various issues reported by the NGOs.

Some of the actions suggested for strengthening the enforcement mechanisms are as follows:

- The functionaries from State agriculture departments implementing the Seed Act including seed laboratories and analysts should also be empowered under EPA to take punitive action.
- The sampling procedures should also be notified to ensure uniform action by the field staff.
- Regular compliance report by companies should be sent to GEAC, SBCCs, DLCs and State Agricultural Universities.
- Field trials should be conducted with the full knowledge and involvement of Gram Sabha, District Magistrate and Block Development Officer.
- Seed testing laboratories should be established and strengthened (at least one per state) and they should be notified as reference laboratories.
- The State agriculture departments should also be notified about the field trials by GEAC with copies of communications addressed to Secretary, Agriculture and Commissioner, Agriculture simultaneously.
- Separate enforcement wings should be established by State Governments to check the spread of illegal Bt cotton.
- Methods for detection of new gene/event integrated in Bt cotton seed need to be developed.

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 Committee is of the view that the present zonal system envisaged by the ICAR is based on several factors such as cotton cultivation practices, agro-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.

d. Rationalization of Biosafety Studies:

The cost towards development of transgenic crops including the biosafety and agronomic studies is as high as Rs 5 crores. With a view to promote the development of transgenic crops from Public Institutions, there is a need to rationalize the data generation from biosafety studies. It is suggested that the risk assessment for some of the parameters may be based on the information available within the country or elsewhere. It is recommended that a Committee be constituted to look into this aspect.

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

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.

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.

S. No.	Name of the participants
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

Annexure-II A

Experimental Trial specifications for multi-location field trials

Design	RBD
No. of replications	3 - 4
No of rows per plot	6
No. of plants per row	minimum 10
Space between plant to plant	60-90 cm (depending on the genotype)
Space between row to row	90-120 cm (“)
Space between replication	2 m
No. of plants per plot	60
Row length (m)	()
Row width (m)	()
Space between experimental area and refuge	2 m
Plot length (m)	()
Plot width (m)	()
Plot size (sq meters)	(L x B)
Bt cotton area (sq meters)	()
Non Bt cotton area	()
Gross experimental area	()

Specifications on entries

Bt cotton tests hybrids
Analogues non-Bt cotton hybrids (where ever available)

Specifications on checks

Recently released Bt cotton as check (zone wise)
National check (non-Bt)
Regional/Zonal check (ruling non Bt cotton hybrid of the zone)

No. of locations

North	-	5
Central	-	8
South	-	6

Annexure-II B

**Common nomenclature indicating gene and event for test entries:
(Few companies were considered, as sample for evolving the system)**

Name of the Company	Existing names of entries	Approved
M/s. Kaveri Seeds, Secunderabad	KCH-135 Bt	KCH135/ MON531
M/s. Ankur Seeds, Nagpur	Ankur 2226 BG	Ankur2226/ MON531
	Ankur 2226 BG II	Ankur2226/ MON15985
M/s. Vikki Agrotech, Hyd	VCH-113 Bt	VCH113/ MON531
M/s. Mahyco, Mumbai	MRC 6100 BG-I	MRC6100/ MON531
	MRC 7341 BG-II	MRC7341/ MON15985
M/s. Rasi Seeds, Attur	RCH-2 Bt	RCH2/ MON531
	IT 301 BGII	IT301/ MON15985
M/s. Nuziveedu, Secunderabad	NCS-914 Bt	NCS914/ MON531
M/s. Tulasi, Guntur	Tulasi-4 Bt	Tulasi4/ MON531
	Tulasi-4 Bt (BG-II)	Tulasi4/ MON15985
M/s. JK Agri Genetics, Hyd	JK Durga Bt	JKDurga / Event1
M/s. Nath Seeds, Aurangabad	NCEH-2R	NCEH2R / -
M/s. Syngenta, Pune	02 – 62 Vip	02-62Vip/ COT202

Annexure-III

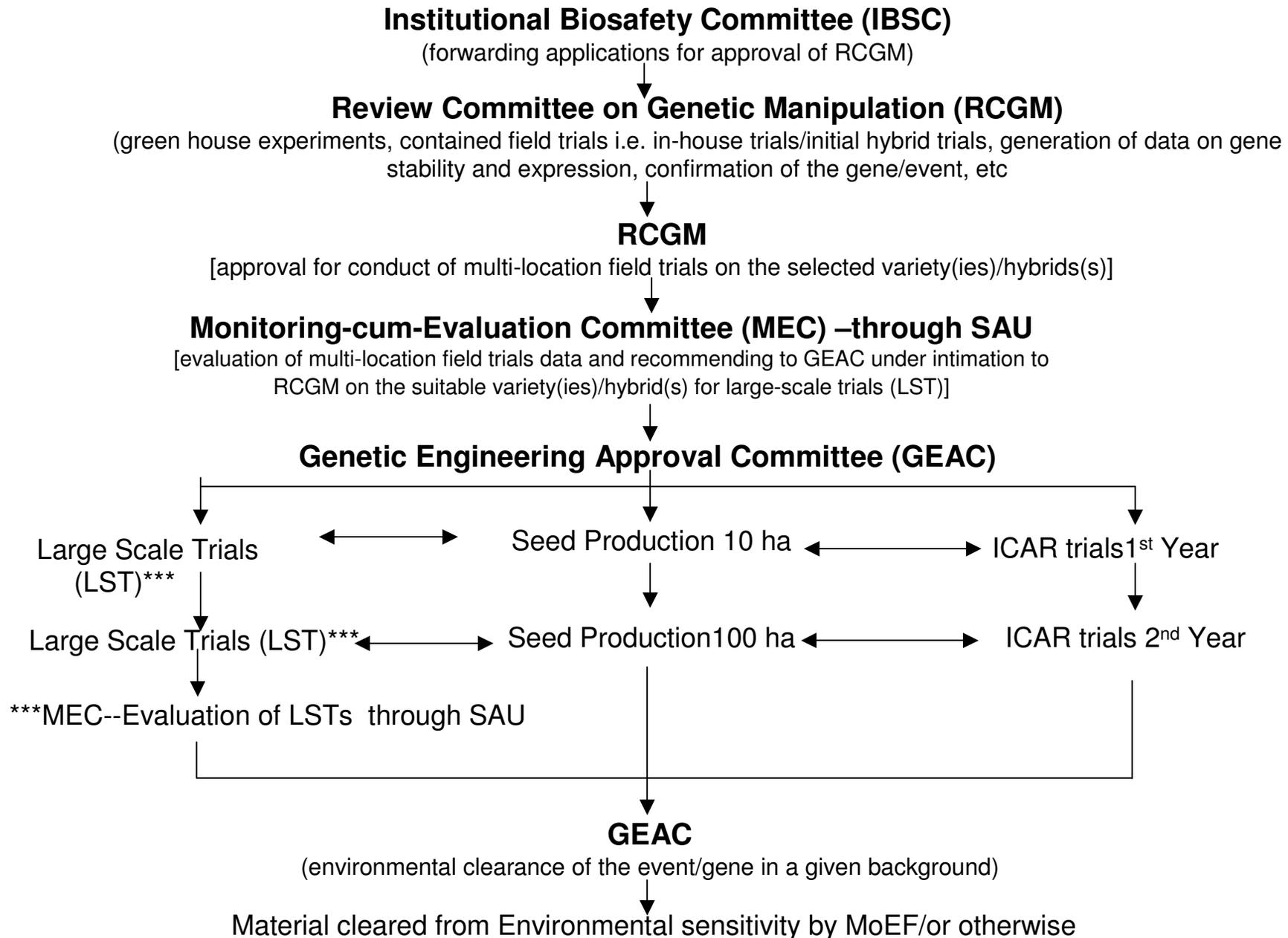
Suggested protocol for SAU testing of Bt cotton hybrids

Location	One
Entries	15 -20 (including checks) per trial
Replications	Three
Plot size	6 rows of 5 m length
Design	Randomized Complete Block Design
Observations	(a) Agronomic data Plant stand, Plant height, Bolls/plant, Boll weight, Seed cotton yield at 135, 150, 165, 180, 195 and 210 DAS as relevant, Lint yield (b) Insect damage data Damage (%) data in fruiting bodies, open bolls, locules (c) Fiber quality data GOT, Staple length, Staple strength, Micronaire, Uniformity ratio, Spinnable counts, CPS

1. Different trials may be organized for early, medium and late maturities as also for rainfed and irrigated conditions
2. Appropriate checks may be defined for each category of trials in each zone
3. Entries should comprise of Bt test entries, two Bt check and one non Bt (Zonal) check
4. Non Bt counterparts of Bt test entries should not be included as entries in the trial
5. If there are more entries than can be accommodated in one trial, then the number of trials in the same location/environment
6. Even with 15 entries and 3 replications, error df will be 28 in the ANOVA using RCBD model
7. Detailed insect larval counts are not required since only the total damage data will reflect the efficacy of the transgene in a hybrid
8. Data on sucking pests and beneficial insects is not needed since it is well established that Bt gene does not have any impact on these two category of insects
9. Days after sowing up to which the seed cotton yield data has to be taken may be specified based on the maturity of hybrids included, target area/location of test, etc.
10. Companies should be allowed to visit the trials in which their entry (ies) is/are being tested

Annexure IV

Flow Diagram on the recommended Procedure for New hybrid/variety with new gene



Annexure – V
PROTOCOL FOR LST

Number of locations for LST.

Cotton hybrids	Zones*		
	Southern	Central	Northern
H X B	10	10	-
a X a	20	30	15
H X H	20	40	20
H X a	10	30	-

H – hirsutum; B – barbadance; h – herbaceum; a – arborium

*To be optimally divided between irrigated, rain-fed and suppressive soils (the trial may also accommodate both normal sown and late sown conditions)

Yield Data Book

Part – A. Pest-predator dynamics

Table A-4: Summary of Beneficial Insect Population of G.M. cotton hybrids & checks

Sl. No.	Hybrid	Beneficial Insects																			
		Candidate Bt					Second Bt					Bt. Check					Hybrid				
		60	90	120	135		60	90	120	135		60	90	120	135		60	90	120	135	
		(Locations _____)																			
1	Quadrat 1																				
2	Coccinellids																				
3	Chrysopa																				
4	Syrphids																				
a	Spider																				
b																					
c																					
		(Locations _____)																			
1	Quadrat 2																				
2																					
3																					
4																					
a																					
b																					
c																					
		(Locations _____)																			
1	Quadrat 3																				
2																					
3																					
4																					

Yield Data Book

Part – B. Yield data

Field note Book - B

Table B-2: Summary of Bartlett's Index & Picking wise Yield of G. M. Cotton Hybrid and check.

Sl. No.	Hybrid	Date of sowing	Seed Cotton Yield - Kg / picking (P) (DAS)						Total Yield (Kg)	Total Yield (Qtl/ha)	Bartlett's Index
			I 120	II 135	III 150	IV 165	V 180	VI (final) >180			
	Entry 1: _____ (Locations _____)										
1											
2											
3											
4											
a											
b											
c											
	Entry 2: _____ (Locations _____)										
1											
2											
3											
4											
a											
b											
c											
	Entry 3: _____ (Locations _____)										
1											
2											
3											
4											
a											
b											
c											
	Entry 4: _____ (Locations _____)										
1											
2											
3											
4											
a	Mean										
b											
c											
Bartlett's Index (B.I.) =			$(6 \times I P + 5 \times II P + 4 \times III P + 3 \times IV P + 2 \times V P + 1 \times VI P)$								

Yield Data Book

Part-C. Fiber and oil details

(see text for sample size and authentic laboratory
for testing on payment basis)

Field note Book - C

Table C-1 : *Summary of fibre properties & oil (%) of G.M. cotton hybrids & checks from three LST (each is a mean of 5 observations).

											Zone :	
Sl. No.	Location / Entry	Ginning out-turn (%)	Seed Index (g)	Lint Index (g)	2.5% Span length (mm)	Uniformity ratio (%)	Fineness (Micro-naire)	Strength 3.2 mm gauge (g/tex)	Spinnable counts	Count Strength Product (CSP)	Oil (%)	
(Locations)												
1	LST-1											
2	Entry A											
3	Entry B											
4	Entry C											
	check											
a												
b												
c												
(Locations)												
1	LST-2											
2	Entry A											
3	Entry B											
4	Entry C											
	check											
a												
b												
c												
(Locations)												
1	LST-3											
2	Entry A											
3	Entry B											
4	Entry C											
	check											
a												
b												
c												
	LSI-4											
	LSI-5											

*To be done by CCTI, Mathunga, Mumbai (Fee to be decided by the Institute)