Decisions taken in the 67th Meeting of the Genetic Engineering Approval Committee held on 22.05.2006.

The 67th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 22nd May 2006 in the Ministry of Environment and Forests under the Chairmanship of Shri B S Parsheera Additional Secretary, MoEF and Chairman GEAC.

1.0 Presentations

1.1 Presentation by M/s Mahyco on the results of the biosafety studies conducted in respect of Bt Brinjal Cry 1 Ac.

1. M/s Mayhco has produced transgenic brinjal plants with cry 1Ac gene from Bacillus thuringiensis tolerant to the fruit and shoot borer, one of the major pests which attack the brinjal crop throughout its life cycle. In accordance with the regulatory requirements, the company has completed biosafety studies to establish environmental and health safety. The data generated from the biosafety studies have been evaluated by the RCGM. The Bt –Brinjal hybrids developed by the Company have also completed the multi-locational trials. M/s Mahyco has been requested to present details of the biosafety data for consideration of the GEAC as they have submitted their application to the GEAC for large scale trials and seed production of four Bt Brinjal hybrids namely MHB-4 Bt, MHB 9 Bt MHB 80 Bt and MHBJ-99 Bt containing cry 1 Ac gene during Kharif 2006. It was informed that the proposal will be placed for consideration of the GEAC after receipt of comments from MEC/RCGM and review of the biosafety data by the GEAC.

2. The Committee invited the representatives of the Company to present the biosafety data. It was informed that cry 1 Ac gene was obtained from Monsanto Co., USA. This gene had been obtained as per the permit dated 16.3.2006 from the DBT. This gene was used to transform the proprietary brinjal line through Agro-bacterium –mediated transformation. The gene was then transferred into other Mahyco brinjal proprietary lines through traditional backcrossing method.

3. The presentation covered the studies carried out by the Company during 2002-2006. The biosafety studies include pollen escape, outcrossing, aggressiveness, germination and weediness, effect on non-target organisms, presence of Cry 1AC protein in soil, effect of Cry1 AC protein on soil micro-flora, and baseline susceptibility studies. The allergenicity studies and toxicological study, conducted include Acute oral toxicity studies in rats, mucous membrane irritation in female rabbit, primary skin irritation test in rabbit, subchronic (90 days) oral toxicity study in Sprague Dawley rats, assessment and allergencity of protein extract using Brown Norway Rats, feeding studies in lactating crossbred dairy cows, effect on the performance and health of broiler chickern, responses as a dietary feed ingredient to common carp growth performance, substantive equivalence studies, compositional analysis, food cooking and protein estimation in cooked fruits. The other studies include protein expression in leaf, shoot, calyx, fruit, stem, and root tissues, molecular characterization, chemical fingerprinting of Bt and non-Bt brinjal, multi-location trials and testing under ICAR system. The following points were noted:

a) The pollen flow study revealed that outcrossing occurred maximum only upto a distance of 20 m.
b) No significant difference in germination, aggressiveness as well as weediness as compared to non Bt. brinjal.
c) Bt Brinjal do not have any toxic effects on the non-target species, namely sucking pests (aphids, jassids, white fly and mites), beetle and beneficial insects.
d) Bt protein was not detected in soil samples indicating that Bt protein is rapidly degraded in the soil.

e) There was no significant difference in population of microbes and soil invertebrates like cultivable bacterial and fungal population, cellembola and earthworm populations, soil nematode population and Gllembola between Bt and non-Bt soil samples.

f) There is no change in the composition of fruit tissue of Bt and non Bt brinjal with respect to proteins, carbohydrates, oil, calories, moisture and ash content.

g) No significant differences in feed consumption, animal weight gain and general animal health were found between animals fed with Bt brinjal.

h) The toxicity and allergencity studies conclude that Bt brinjal did not cause any toxicity and based on the irritancy index the Bt Brinjal may be classified as non-irritant to skin and mucous membrane in rabbits. It was noted that intradermal injections of protein extract of Bt Brinjal showed allergencity and inflammatory characteristic and this was similar to the allergencity and inflammatory characteristic exhibited by the non bt Brinjal.

i) Feeding experiments conducted with Bt brinjal on chicken, cows and buffaloes indicated that Bt brinjal is nutritionally equivalent, wholesome and safe as the non-Bt brinjal.

j) The protein expression varied between 5 to 47 ppm in shoots and fruits.

k) The Baseline susceptibility data generated for 29 populations indicate that the average MICS was 0.059 ppm (range 0.020 to 0.140 ppm).

l) Detection of protein in uncooked Bt brinjal was noted to be positive. In respect of roasted, steamed, shallow fried and deep fried the presence of protein by ELISA was detected as negative. It was clarified that Bt protein was detectable in uncooked Bt brinjal for five days after harvesting.

m) The chemical fingerprinting of Bt and non-Bt indicate no appreciable variation in relative abundance of alkaloids between Bt and Non Bt brinjal.

n) The multi-location trial data also indicate that the incidence of Fruit and Shoot Borer is significantly lower in the Bt hybrids as compared to non-Bt brinjal.

o) The marketable yield of Bt brinjal was than the non-Bt brinjal.

4. During the deliberations one of the Expert members suggested the analysis of fruit dry matter be carried out to determine differences in yield from the agronomic trials in order to assess the yields from Bt and check entries. After discussion, it was agreed that since substantial equivalence has been carried out in which moisture is one of the components, and there are no differences reported for Bt and non-Bt for moisture, that this may not be needed. It was noted that the feeding studies were conducted with only Bt brinjal fruit. The need for conducting leaf feeding studies on goats was also discussed. The Company representative clarified that the expression level of cry1Ac is higher in fruits than in leaves and there is compositional equivalence in all plant parts between Bt and non-Bt. Also the adverse effects which are associated with the Bt protein in fruits and leaves would be the same. Director CFTRI emphasized that Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits also needs to be carried out. On the issue of the insert copy number and how the Southern analysis was done it was clarified that brinjal DNA was cut with a unique cutter in the insert and the probe used was the cry1Ac gene specific probe. One of the Expert Members also advised the Company to review if the highest MIC95 value should be kept for monitoring rather than the average for the target pest vis-à-vis Cry1Ac protein expression levels.

5. After detailed deliberation, it was decided that the above issues may be considered by the Committee while deliberating on the formal proposal submitted by the applicant for LST and if necessary additional studies may be included in the protocol for large scale trials. The Committee also opined that the detailed biosafety data be posted on MoEF website and comments received may be placed before the GEAC.

1.2 Implementation of Supreme Court Order dated 1.5.2006 in respect of WP NO 260/2005 – Aruna Rodrigues & Others Vs union of India and others.

1. The Member Secretary briefed the Committee on the genesis of the Hon'ble Supreme Court Order dated 1.5.2006 wherein the Court has directed that "till further orders, field trials of genetically modified organisms shall be conducted only with the approval of the GEAC". It was explained that

RCGM has been authorized to approve controlled multi-locationl field trials (MLT) by the GEAC in its 19th meeting held on 8.3.1999. Since then the practice of RCGM approving multi-location trials and GEAC approving large scale trials (LST) has been going on. It was further informed that, the Ministry is in the process of filing an affidavit to revise the court order. During the interim period compliance of the directions issued by the Supreme Court is mandatory.

2. The Chairman requested Prof G Hegde, National Law School to give his considered opinion on the implementation of the Court Order. He informed the Committee that the 'Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Micro-Organisms or Cells of 1989' framed pursuant to the relevant provisions of the Environment (Protection) Act, 1986, provided for constituting, among other statutory bodies, the Review Committee on Genetic Manipulation (RCGM) and the GEAC. At present, the above named statutory authorities have demarcated the scope of their functions in giving authorization. While the RCGM- that comes under the Bio-technology Department- is authorized to approve submissions for controlled multi-location field trails, the GEAC, which is a body under the Department of Environment, Forest, and Wildlife- is empowered to approve applications/proposals for large-scale trails and for environment release. The ad Interim Order of the apex court makes prior approval of the GEAC as mandatory and the same must be followed by the RCGM and the GEAC.

3. The request received from the Member Secretary, RCGM, to vet the Minutes of RCGM in respect of applications for field trials of GMOs was also discussed at length. The Expert Member opined that "in view of the apex courts' Order the GEAC has not only to deliberate on the minutes of the RCGM but it has to follow the procedural mechanisms specially designed for its deliberation on the proposals for environmental release and also others before giving its approval to the minutes of the RCGM".

4. In view of the above and in compliance of the Court order, the Committee directed RCGM to forward its recommendations in respect of applications received for MLT. The Member Secretary, RCGM informed the Committee that recommendations of RCGM in respect of 91 proposals for MLT have been approved by the RCGM prior to 1. 5.2006. However, formal clearance order has not been issued. He requested the Committee to consider the recommendation of RCGM in respect of these proposals. After detailed deliberation and taking into consideration the recommendations of RCGM, the Committee approved the decision of RCGM and authorized Member Secretary, RCGM to issue the requisite communications in this regard.

5. The Member Secretary, GEAC also informed the Committee that many applicants have been directly approaching the GEAC for approval of MLT. The Committee considered the request of M/s Metahelix life Sciences Private Limited and others and noted that the proposals have been placed for discussion in the RCGM meeting to be held on 23.5.2006. It was decided that RCGM may continue to evaluate the proposal for MLT. However in compliance with the Supreme –Court order its recommendations should be forwarded to the GEAC for its consideration and approval before clearance for MLT is accorded. This procedure would apply in all future cases for approval of MLT, till the Court order is revised.

6. The Member Secretary RCGM informed the Committee that the sowing season in respect of certain crops would be over as the GEAC is likely to meet only after one month. In view of the seasonality involved, it was decided that a special meeting of the GEAC be convened on 1st June 2006 to consider the proposals referred to RCGM for MLT.

1.3 Clarification sought by State Govt of Madhya Pradesh on whether the Bt cotton hybrids approved for commercial release can be sold by other Companies in different brand names.

1. The Committee considered the representation received from the State Govt of Madhya Pradesh regarding the sale of GEAC approved Bt cotton by various Companies in different brand

names. It was noted that as per section 2 (3) sub para (1) point (c), rules 1989 is applicable for specific cases which includes production manufacturing, processing, storage, import, drawing off, package and repackages. During the deliberations, it was pointed out that some of the hybrids approved by the GEAC have both a brand name as well as a number. In many of the cases only a number has been indicated.

2. After detailed deliberations it was agreed that there should be no change in the brand name approved by the GEAC. In respect of hybrids approved by the GEAC without a brand name, the Company may be advised to inform the GEAC and seek its approval. It was also agreed that views of the State Govt on the matter may be obtained

Additional Agenda under Policy issue

1.4 Import of GM Soy bean oil.

1. The Member Secretary informed that, the interim decision of the GEAC requesting importers of GM Soy bean oil to submit requisite certification and analytical report has been communicated to the oil trade industry and others. In response the oil importers have sought clarification on whether it is a case by case approval for each importer, the sampling methodology and size of sample for testing, documentation to accompany the shipment.

3. It was agreed that the oil trade industry association on behalf of all importer may seek one time approval of GEAC for import of GM soy bean oil derived from Round up Ready Soybean. The samples may be drawn as per the procedure prescribed under PFA. Subsequent to the GEAC approval, the documents accompanying a shipment should include the following details:

a. Name of the importer and contact details.
b. The Country from where it is imported.
c. Declaration that it contains GM soybean oil derived only from Round up Ready Soybean.
d. GEAC approval no and date.

During the deliberation, it was pointed out by Director CFTRI that the 'one time' GEAC clearance for GM soy bean oil may be construed as an exemption from other requirements under PFA. Therefore the GEAC approval for GM soybean oil, should be subject to compliance of the requirement under PFA.

He further explained that analysis of oil derived from GM source would not serve any purpose, as detection of DNA/ proteins in highly processed food like oil is not feasible and based on the analytical report the origin (GM/NON-GM source) from which oil has been derived cannot be indicated. He suggested that when the samples are sent for analysis it should be clearly indicated that this is not being requested to test for GM but test for the normal oil as per the specifications of PFA. Otherwise there will be confusion for asking the laboratory to test for "GM clearance" and in turn laboratories would reject the request as GM clearance for oil cannot be given in the present level of Science and regulations on PFA. The Committee agreed with the above suggestion but also opined that in addition to the parameters specified by PFA, the Committee would like to know the level of herbicide in the residue after the oil is refined.

1.5 Recommendations of the sub-Committee on Bt Cotton and Related Issues

1. The Member Secretary informed the Committee that 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 NRC on Plant Biotechnology, IARI, Pusa, New Delhi. The recommendations of the sub-Committee in respect of the regulatory process for Cry 1 Ac gene (Mon 531) and other related issues were presented for consideration of the Committee. It was further

explained that this is an interim report as the Committee is yet to take a view on several other issues referred in the TOR. Dr Mayee, Co-Chair GEAC and Chairman of the sub-Committee explained the rationale behind the revised procedure for Bt cotton containing cry 1 Ac gene.

2. While there was a general consensus on the recommendation of the sub-Committee, the representative of ICAR informed that ICAR does not agree with the revised procedure and suggested that the present practice of testing under RCGM/ICAR/GEAC should continue. ICAR was requested to view the revised procedure in light of the limited resources and facilities available with ICAR. Views were also expressed that that there is an urgent need to optimize the resources for evaluating the biosafety of new products. The advantages and disadvantages of the existing and proposed system were deliberated at length.

3. After detailed discussion there was a general consensus among the Members (except ICAR) on the adoption of the sub-Committee recommendation. However some fine tuning of the recommendations made in respect of SAU trials is required for which the sub-Committee may consult the SAUs. It was agreed that representatives of SAU may be invited for the next meeting of the sub-Committee. The issue of applicability of the new procedure was also discussed. It was agreed that the recommendations would be applicable perspectively. 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. Clarification was sough by one of the Members on whether the norm fixed by the GEAC in respect of the yield would apply to the new procedure also. It was clarified that the present norm being followed would apply unless otherwise recommended by the sub-Committee or the decision to revise the same is taken at a future date. The Committee also requested the sub-Committee to indicate a bench mark for evaluating the superiority of the hybrid based on fibre length and quality.

4. The Member Secretary placed before the Committee the request for approval of the following hybrids under the new procedure and also presented the facts of the case:

a. Commercial release of KDCHH 9810 Bt in the Central and South zone.
b. Commercial release of KDCHH 9632 Bt in the Central zone
c. Commercial release of KDCHH 9821 Bt in the Central zone
d. Commercial release of NCS 913 Bt in the Central zone
e. Commercial release of NCS 138 Bt in the Central zone
f. Commercial release of NPH 2171 Bt in the Central zone
g. Commercial release of Tualsi 117 Bt in the Central zone

5. Since the report of the sub-Committee is only an interim report and in light of the decision taken by the Committee at para 3, decision on the request at para 4 was deferred.

2.0 Consideration of proposals related to transgenic crops.

I. COMMERCIAL REALEASE IN SOUTH ZONE

1. The GEAC considered the proposals for commercial release (Agenda Item 5.1 to 5.13) in the light of the GEAC decisions taken in the meeting held on 4.4.2006 and 2.5.2006. It was noted that in the previous meetings, the GEAC had approved Bt cotton hybrids fulfilling the following criteria for commercial release in the Central and North zones.

a. Hybrid has completed one year LST.
b. Hybrid has been recommended by MEC for cultivation in the South zone
c. Hybrid has completed two years of ICAR trials and in case of notified varieties one year of ICAR trials.
d. Hybrid containing released gene event recording a yield upto 5 % less than the best Bt check under irrigated/rainfed conditions in protected conditions.

e. Hybrid containing new gene event recording a yield upto 10 % less than the best Bt check under irrigated/rainfed conditions protected conditions.

2.1 Permission for commercial release of Bt Cotton hybrid GK- 207 Bt and GK-209 Bt containing cry 1Ac gene (Mon 531 event) by M/s Ganga Kaveri,

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2.2 Permission for commercial release of transgenic cotton hybrids ACH-33-1 and ACH–155-1 containing Cry 1Ac gene (Mon 531 event) by M/s Ajeet Seeds Ltd.

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2.3 Permission for commercial release of transgenic cotton hybrids RCH-111 BG I, RCH-371 BG I containing Cry 1Ac gene (Mon 531) event by M/s Rasi Seeds Ltd.

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2.4 **Permission for commercial release of transgenic cotton hybrids RCHB-708 BG I containing Cry 1Ac gene (Mon 531) event by M/s Rasi Seeds Ltd**.

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2.5 Permission for commercial release of transgenic cotton hybrids Brahma Bt and Paras Laxmi containing Cry 1Ac gene (Mon 531) event by M/s Emergent Seeds Ltd.

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2.6 Permission for commercial release of transgenic cotton hybrids NCS-913 Bt containing Cry1 Ac gene (MON 531 event) by M/s Nuziveedu Seeds Ltd.

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2.7 Permission for commercial release of transgenic cotton hybrids PRCH-102 Bt and PRCH-103 Bt containing Cry1 Ac gene (MON 531 event) by M/s Pravardhan Seeds Ltd.

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2.8 Permission for commercial release of transgenic cotton hybrids PCH-2270 Bt and PCH 2171 Bt containing Cry1 Ac gene (MON 531 event) by M/s Prabhat Seeds Ltd.

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2.9 **Permission for commercial release of transgenic cotton hybrids KDCHH-9632 Bt containing Cry1 Ac gene (MON 531 event) by M/s Krishidhan Seeds**.

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2.10 Permission for commercial release of transgenic cotton hybrids MRC-7351 BG II and MRC – 7201 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II by M/s Mahyco.

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2.11 **Permission for commercial release of transgenic cotton hybrid NCEH-3 R containing encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Nath Seeds Ltd**.

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2.12 Permission for commercial release of transgenic cotton hybrids JK - Durga and JKCH - 99 containing cry 1Ac gene (Event-1) by M/s JK Seeds Ltd.

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2.13 Permission for commercial release of transgenic cotton hybrids MRC – 7347 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event)—BG-II by M/s Mahyco

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2.14 Permission for commercial release of transgenic cotton hybrids VICH 5 BG-I AND VICH 9 BG-I containing Cry 1Ac gene (Mon 531 event) by M/s Vikram Seeds Limited.

1. The Committee considered the request for commercial release in the South zone with GK-207 Bt and GK-209 Bt by M/s Ganga Kaveri, ACH-33-1 and ACH–155-1 by M/s Ajeet Seeds Ltd, RCH-

111 BG I, RCH-371 BG I by M/s Rasi Seeds Ltd, RCHB-708 BG I by M/s Rasi Seeds Ltd, Brahma Bt and Paras Laxmi by M/s Emergent Seeds Ltd., NCS-913 Bt by M/s Nuziveedu Seeds Ltd., PRCH-102 Bt and PRCH-103 Bt) by M/s Pravardhan Seeds Ltd., PCH-2270 Bt and PCH 2171 Bt by M/s Prabhat Seeds Ltd., KDCHH-9632 Bt by M/s Krishidhan Seeds., MRC-7351 BG II and MRC – 7201 BG II by M/s Mahyco, NCEH-3 R by M/s Nath Seeds Ltd., JK - Durga and JKCH - 99 by M/s JK Seeds Ltd, MRC – 7347 BG II by M/s Mahyco and VICH 5 BG-I & VICH 9 BG-I by M/s Vikram Seeds Limited.

2. The Member Secretary GEAC informed that the 21 Bt cotton hybrids under consideration for commercial release in the South zone have completed the LST during Kharif 2005. The LST have been evaluated by the MEC. Based on the results of the field trials, MEC in its meeting held on 20-21 April 2006 has recommended 18 Bt cotton hybrids for commercial cultivation in the South zone namely GK- 207 Bt, GK-209 Bt, ACH-33-1, ACH–155-1, RCH-111 BG I, RCH-371 BG I, RCHB-708 BG I, Brahma Bt, NCS-913 Bt , PCH-2270 Bt, PCH 2171 Bt, KDCHH-9632 Bt, MRC-7351 BG II, MRC – 7201 BG II, NCEH-3 R, JK – Durga, JKCH – 99, MRC – 7347 BG II and VICH 5 BG-I & VICH 9 BG-I subject to completion of the regulatory requirements. It was also noted that the report of the MEC has been considered in the RCGM meeting held on 25.4.2006. The RCGM has endorsed the recommendations of MEC.

3. The Committee also considered the results of the ICAR trials and the yield of the hybrid in light of the norm fixed by the Committee. After detailed deliberations and taking into consideration the findings of the LST and recommendations made by MEC/ RCGM / ICAR and in accordance with decisions taken in the previous GEAC meeting the following decisions were taken by the GEAC:

A. GEAC accorded approval for commercial cultivation of the following hybrids in the South zone for a period of three years:-

a. Under Rainfed and Under Irrigated conditions:

- GK-209 Bt containing cry 1Ac gene (Mon 531 event) by M/s Ganga Kaveri.
- RCH-111 BG I containing cry 1Ac gene (Mon 531 event) by M/s Rasi Seeds Ltd.
- RCH-371 BG I containing cry 1Ac gene (Mon 531 event) by M/s Rasi Seeds Ltd.
- RCHB-708 BG I containing cry 1Ac gene (Mon 531 event) by M/s Rasi Seeds Ltd.
- Brahma Bt containing cry 1Ac gene (Mon 531 event) by M/s Emergent Seeds Ltd.
- NCS-913 Bt containing cry 1Ac gene (Mon 531 event) by M/s Nuziveedu Seeds Ltd.
- MRC-7351 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event) by M/s Mahyco.
- MRC– 7201 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event) by M/s Mahyco.
- NCEH-3 R containing encoding fusion genes (cry 1Ab+Cry Ac) ' GFM by M/s Nath Seeds Ltd.
- JK - Durga containing cry 1Ac gene (Event-1)by M/s JK Seeds Ltd.
- JKCH - 99 containing cry 1Ac gene (Event-1)by M/s JK Seeds Ltd.

b. Under Irrigated conditions:

- GK- 207 Bt containing cry 1Ac gene (Mon 531 event) by M/s Ganga Kaveri
- ACH-33-1 Bt containing cry 1Ac gene (Mon 531 event) by M/s Ajeet Seeds Ltd
- PCH-2270 Bt containing cry 1Ac gene (Mon 531 event) by M/s Prabhat Seeds Ltd.
- KDCHH-9632 containing cry 1Ac gene (Mon 531 event) Bt by M/s Krishidhan Seeds.
- VICH 5 Bt containing cry 1Ac gene (Mon 531 event) by M/s Vikram Seeds Limited.

The following hybrid was approved for Central zone under irrigated conditions.

- MRC – 7347 BG II containing stacked genes Cry1 Ac and Cry 2Ab (MON 15985 event) by M/s Mahyco.

c. Under Rainfed conditions:

- None

B. In respect of PRCH-102 Bt and PRCH-103 Bt by M/s Pravardhan Seeds Ltd. it was noted that MEC has deferred its decision as there was certain discrepancy in the boll count and conduct of trials in the South zone. The Member Secretary RCGM informed the Committee that the matter is being reconsidered in the RCGM meeting to be held on 23.5.2006. The Committee noted that as per ICAR trials and the norm fixed by the Committee, PRCH 102 Bt is suitable for irrigated conditions and PRCH 103 Bt is suitable for both irrigated and rain-fed conditions. The Committee approved the hybrids for the specific agro-climatic conditions subject to MEC/ RCGM recommendations.

C. GEAC did not approve PCH 2171 Bt by M/s Prabhat Seeds Ltd., and VICH 9 Bt by M/s Vikram Seeds Limited.
as the yield was less than the norm fixed by the Committee.

D. In respect of ACH–155-1 by M/s Ajeet Seeds Ltd the Committee was of the view that the request for commercial release is pre-mature as it has not completed the requirement of two years ICAR trials.

E. GEAC did not approve Paras Laxmi by M/s Emergent Seeds Ltd as the hybrid was not found suitable for release in the South zone by MEC based on the LST data.

3.0 Commercial Release (Reconsideration Case)

3.1 Permission for Renewal commercial release of Bt Cotton hybrid MECH-12Bt containing cry 1Ac gene Mon 531 event only in A P by M/s Mahyco.

1. The Committee considered the request for renewal of GEAC permission for MECH 12 Bt in Andhra Pradesh and the justification provided by the Company. It was noted that the GEAC in its meeting held on 3.5.2005 decided not to approve any of the three hybrids (MECH 12 Bt, MECH 162 Bt and MECH 184 Bt) for the State of Andhra Pradesh based on the recommendations received from the State Govt.

2. In light of the MRTPC case and the stand taken by the State Govt of AP, the Committee decided to refer the matter to the State Govt and seek clarification on why the request for renewal of MECH 12 BT should not be considered.

4.0 LARGE SCALE TRIALS IN SOUTH ZONE Hybrids

1.0 The GEAC considered the proposals for large scale trials (Agenda Item 5.15 to 5.43) in light of the GEAC decisions taken in the meeting held on 4.4.2006 and 2.5.2006. It was noted that in the previous meetings, the GEAC had approved Bt cotton hybrids fulfilling the following criteria for LST in the Central and North zones.

a. Completion of multi-locational trials under RCGM.

b. Recommendation of MEC and RCGM on the suitability of the hybrid for a specific zone based on the MEC evaluation multi-locational trials.

c. Since ICAR has informed that the maximum numbers of hybrids that can be included in the AICCIP trials are about 25 per zone including the checks, it was decided to advice the applicant to forward only one of their best Bt hybrid for testing under ICAR trials. The hybrid so selected by the Company would enter ICAR and LST during Kharif 2006.

d. The LST would be conducted at 40 locations in the North zone, 60 locations in the Central Zone and 40 locations in the South zone for a period of 2 years as per the protocol recommended by Dr S Nagarajan Committee.

e. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

4.1 Permission for large scale trials and seed production of transgenic cotton hybrids-Tulsi-4 Bt, Tulsi-117 Bt, Tulasi-9 Bt, Tulsi-5 Bt and Tulsi-18 Bt containing Cry 1Ac gene (MON-531 event) by M/s Tulasi Seeds.

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4.2 Permission for large scale trials and seed production of transgenic cotton hybrids-302 Bt and 322 Bt containing Cry 1Ac gene (MON-531 event) by M/s Bioseeds Research India Ltd.

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4.3 Permission for large scale trials and seed production of transgenic cotton hybrids-Singma, Dyna and Ole containing Cry 1Ac gene (MON-531 event) by M/s Vibha Seeds.

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4.4 Permission for large scale trials and seed production of transgenic cotton hybrids-MLCH -317 BG and MLCH 318 BG containing Cry 1Ac gene (MON-531 event) by M/s Emergent Research India Ltd.

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4.5 Permission for large scale trials and seed production of transgenic cotton hybrids-PCH – 917, PCH - 923 and PCH - 930 containing Cry 1Ac gene (MON-531 event) by M/s Prabhat Agri.

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4.6 Permission for large scale trials and seed production of transgenic cotton hybrids-Rudra-Bt, PRCH-31 Bt, containing Cry 1Ac gene (MON-531 event) by M/s Pravardhan Seeds.

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4.7 Permission for large scale trials and seed production of transgenic cotton hybrids-Nandi- 405, Nandi- 36 and Nandi-45 Bt, containing Cry 1Ac gene (MON-531 event) by M/s Nandi Seeds.

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4.8 Permission for large scale trials and seed production of transgenic cotton hybrids VCH- 111 Bt, VCH-113 containing Cry 1Ac gene (MON-531 event) by M/s Vikki's Agrotech Private Limited.

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4.9 Permission for large scale trials and seed production of transgenic cotton hybrids Ankur-Jai BG, Sita BG and Akka BG containing Cry 1Ac gene (MON 531 event) by M/s Ankur Seeds.

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4.10 Permission for large scale trials and seed production of transgenic cotton hybrids NCS-914 Bt,NCS-915 Bt, NCS-929Bt containing Cry 1Ac gene (MON-531 event) by M/s Nuziveedu Seeds.

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4.11 Permission for large scale trials and seed production of transgenic cotton hybrids NCHB-940 Bt, NCHB-944 Bt, NCHB-945 Bt containing Cry 1Ac gene (MON-531 event) by M/s Nuziveedu Seeds.

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4.12 Permission for large scale trials and seed production of transgenic cotton hybrids KCH- 135 Bt,KCH-707Bt, and KCH-119 Bt containing Cry 1Ac gene (MON-531 event) by M/s Kaveri Seeds.

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4.13 Permission for large scale trials and seed production of transgenic cotton hybrids-Tulsi-4 BGII, Tulasi-9 BGII, and Tulsi-117 BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Tulasi Seeds.

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4.14 Permission for large scale trials and seed production of transgenic cotton hybrids-302-2 and 322-2 Bt containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Bioseeds.

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4.15 Permission for large scale trials and seed production of transgenic cotton hybrids-RCH-2 BGII, RCH - 557 BG II and RCH – 560 BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Rasi Seeds.

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4.16 Permission for large scale trials and seed production of transgenic cotton hybrids-ACH-33-2, ACH - 155-2 and ACH – 21-2 containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Ajeet Seeds.

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4.17 Permission for large scale trials and seed production of transgenic cotton hybrids-Bharma BG II Chetana BGII and Atal BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Emergent.

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4.18 Permission for large scale trials and seed production of transgenic cotton hybrids-MRC-7929 BGII and MRC-7918 BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Mahyco.

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4.19 Permission for large scale trials and seed production of transgenic cotton hybrids NCS-145 BGII, NCS-207 BGII, NCS-913 BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Nuziveedu Seeds.

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4.20 Permission for large scale trials and seed production of transgenic cotton hybrids Ankur-651 BGII, Akka BGII AND Sita BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Ankur Seeds.

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4.21 Permission for large scale trials and seed production of transgenic cotton hybrids KDCHH-441 BG-II, KDCHH -999 BG-II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Krishidhan seeds.

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4.22 Permission for large scale trials and seed production of transgenic cotton hybrids NCEH-2R, NCEH-13 Bt ,NCEH-14 Bt, NHH-44 Bt, Kashinath Bt encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Nath Seeds Ltd.

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4.23 Permission for large scale trials and seed production of transgenic cotton hybrids Dhruv Bt (ZCH – 50064), Polaris Bt (ZCH – 50081) and K – 5038 Bt (ZCH - 50067) containing encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Zuari Seeds Ltd.

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4.24 Permission for large scale trials and seed production of transgenic cotton hybrids- JK – Gowri, JKCH – 634 (Ishwar) Bt, JKCH – 2004 Bt and JK – Chamundai Bt containing Cry 1Ac gene (MON-531 event) by M/s JK Seeds.

1. The Committee considered the request for large scale trials in the South zone with Tulsi-4 Bt, Tulsi-117 Bt, Tulasi-9 Bt, Tulsi-5 Bt and Tulsi-18 Bt by M/s Tulasi Seeds, 302 Bt and 322 Bt by M/s Bioseeds Research India Ltd, Singma, Dyna and Ole by M/s Vibha Seeds, MLCH -317 BG and MLCH 318 BG by M/s Emergent Research India Ltd, PCH – 917, PCH - 923 and PCH - 930 by M/s Prabhat Agri, Rudra-Bt, PRCH-31 Bt by M/s Pravardhan Seeds, Nandi- 405, Nandi- 36 and Nandi-45 Bt by M/s Nandi Seeds, VCH- 111 Bt, VCH-113 by M/s Vikki's Agrotech Private Limited, Ankur-Jai BG, Sita BG and Akka BG by M/s Ankur Seeds, NCS-914 Bt,NCS-915 Bt, NCS-929Bt by M/s Nuziveedu Seeds, NCHB-940 Bt, NCHB-944 Bt, NCHB-945 Bt by M/s Nuziveedu Seeds, KCH- 135 Bt,KCH-707Bt, and KCH-119 Bt by M/s Kaveri Seeds, VICH-5 Bt and VICH-9 Bt by M/s Vikram Seeds Ltd, Tulsi-4 BGII, Tulasi-9 BGII, and Tulsi-117 BGII by M/s Tulasi Seeds, 302-2 and 322-2 Bt by M/s Bioseeds, RCH-2 BGII, RCH - 557 BG II and RCH – 560 BG II by M/s Rasi Seeds, ACH-33-2, ACH - 155-2 and ACH – 21-2 by M/s Ajeet Seeds, Bharma BG II Chetana BGII and Atal BGII by M/s Emergent, MRC-7929 BGII and MRC-7918 BGII by M/s Mahyco, NCS-145 BGII, NCS-207 BGII, NCS-913 BGII by M/s Nuziveedu Seeds, Ankur-651 BGII, Akka BGII AND Sita BGII by M/s Ankur Seeds, KDCHH-441 BG-II, KDCHH -999 BG-II by M/s Krishidhan seeds, NCEH-2R, NCEH-13 Bt ,NCEH-14 Bt, NHH-44 Bt, Kashinath Bt M/s Nath Seeds Ltd, Dhruv Bt (ZCH – 50064), Polaris Bt (ZCH – 50081) and K – 5038 Bt (ZCH - 50067) by M/s Zuari Seeds Ltd, JK – Gowri, JKCH – 634 (Ishwar) Bt, JKCH – 2004 Bt and JK – Chamundai Bt by M/s JK Seeds.

2. The Committee noted that the above mentioned hybrids have completed the multi-locational field trials under RCGM. The field trials have been evaluated by the MEC and the results discussed in the MEC meeting held on April 20-21, 2006. It was noted that out of the 71 Bt cotton hybrids tested under multi-locational trials, MEC has recommended 54 Bt cotton hybrids namely for LST in the South zone. It was also noted that the report of the MEC has been considered in the RCGM meeting held on 25.4.2006. The RCGM has endorsed the recommendations of MEC.

3. After detailed deliberations and taking into consideration the findings of the mulit-location trials and recommendations made by RCGM and MEC and in accordance with the decisions taken in the previous GEAC meetings, the following decisions were taken:

a. The GEAC found the following hybrids suitable for large scale trials in the South zone.

- Tulsi-4 Bt, Tulsi-117 Bt containing Cry 1Ac gene (MON-531 event) by M/s Tulasi Seeds.
- 302 Bt and 322 Bt containing Cry 1Ac gene (MON-531 event) by M/s Bioseeds Research India Ltd.
- Sigma, Dyna and Ole containing Cry 1Ac gene (MON-531 event) by M/s Vibha Seeds.
- PCH – 917 and PCH - 930 containing Cry 1Ac gene (MON-531 event) by M/s Prabhat Agri.

- Rudra-Bt, PRCH-31 Bt containing Cry 1Ac gene (MON-531 event) by M/s Pravardhan Seeds.
- Nandi- 405, Nandi- 36 containing Cry 1Ac gene (MON-531 event) by M/s Nandi Seeds.
- VCH- 111 Bt, VCH-113 containing Cry 1Ac gene (MON-531 event) by M/s Vikki's Agrotech Private Limited.
- Ankur-Jai BG, Sita BG containing Cry 1Ac gene (MON-531 event) by M/s Ankur Seeds.
- NCS-915 Bt, NCS-929 Bt containing Cry 1Ac gene (MON-531 event) by M/s Nuziveedu Seeds.
- NCHB-940 Bt, NCHB-944 Bt, NCHB-945 Bt containing Cry 1Ac gene (MON-531 event) by M/s Nuziveedu Seeds.
- KCH- 135 Bt, KCH-707 Bt containing Cry 1Ac gene (MON-531 event) by M/s Kaveri Seeds.
- Tulsi-4 BG II, Tulasi-9 BG II, and Tulsi-117 BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Tulasi Seeds.
- 302-2 and 322-2 Bt containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Bioseeds.
- RCH-2 BG II and RCH - 557 BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Rasi Seeds.
- ACH-33-2 and ACH - 155-2 containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Ajeet Seeds.
- Bharma BG II and Atal BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Emergent.
- MRC-7929 BGII and MRC-7918 BGII containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Mahyco.
- NCS-145 BG II, NCS-207 BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Nuziveedu Seeds.
- Ankur-651 BG II and Akka BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Ankur Seeds.
- KDCHH-441 BG-II and KDCHH -999 BG-II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Krishidhan seeds.
- NCEH-2R, NCEH-13 Bt and Kashinath Bt encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Nath Seeds Ltd.
- Dhruv Bt (ZCH – 50064) and Polaris Bt (ZCH – 50081) containing encoding fusion genes (cry 1Ab+Cry Ac) ` GFM by M/s Zuari Seeds Ltd.
- JK – Gowri, JKCH – 634 (Ishwar) Bt and JK – Chamundai Bt containing Cry 1Ac gene (Event 1) by M/s JK Seeds.

b. Since ICAR has informed that the maximum numbers of hybrids that can be included in the AICCIP trials are about 25 per zone including the checks, it was decided to advice the applicant to forward only one of their best Bt hybrid for testing under ICAR trials. The hybrid so selected by the Company would enter ICAR and LST during Kharif 2006.

c. The LST would be conducted at 40 locations in the South Zone for a period of 2 years as per the protocol recommended by the Committee in the previous GEAC meetings.

d. The GEAC also approved seed production in an area of 10 ha during first year LST and in an area of 100 ha during second year LST.

e. In respect of NHH- 44 it was noted that the hybrid has been released by Parbhani Agriculture University, Nanded and has been identified as national check. The Committee was informed that the request for LST with NHH 44 in the Central zone was considered by the committee in the previous meeting wherein it was decided, to protect the IPR of the Public funded institutions, NOC/permission from the Agriculture University need to be obtained in the first instance. The Committee decided to await the response of the State Agriculture University. Decision on the request was therefore deferred.

f. GEAC did not approve Tulasi-9 Bt, Tulsi-5 Bt and Tulsi-18 Bt , MLCH -317 BG and MLCH 318 BG, PCH – 923, Nandi-45 Bt, Akka BG, NCS-914 Bt, KCH-119 Bt , RCH – 560 BG II, ACH – 21-2, Chetana BGII, NCS-913 BGII Sita BGII , NCEH-14 Bt, K – 5038 Bt (ZCH - 50067), JKCH – 2004 Bt as the MEC did not recommend the hybrids for LST in the South zone based on the MLT data.

5.0 REQUEST FOR SECOND YEAR LST IN THE SOUTH ZONE

5.1 ermission for 2nd year large scale trials of transgenic cotton hybrids KDCHH-621 BGII containing stacked genes Cry Ac gene (MON-15985 event) by M/s Krishidhan Seeds Pvt. Ltd.

5.2 Permission for 2nd year large scale trials of transgenic cotton hybrids KDCHH-9810 containing Cry Ac gene (MON-531 event) by M/s Krishidhan Seeds Pvt. Ltd.

5.3 Permission for 2nd year large scale trials and seed production of transgenic cotton hybrids-RCH -530 BG II, RCH - 533 BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) by M/s Rasi Seeds.

1. The Committee considered the request for conduct of second year LST with KDCHH-621 BGII containing stacked genes Cry Ac gene (MON-15985 event) and KDCHH-9810 containing Cry Ac gene (MON-531 event) by M/s Krishidhan Seeds Pvt. Ltd and RCH -530 BG II, RCH - 533 BG II containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) in the South zone . It was noted that the field trials have been monitored by MEC. The MEC has recommended these for commercial release subject to completion of procedural requirement. The second year LST is being requested because the procedural requirement of two year ICAR trials have not been completed.

2. In view of the above stated facts, the GEAC approved the conduct of second year LST with KDCHH-621 BGII, KDCHH-9810, RCH -530 BG II and RCH - 533 BG II in the South zone at 40 locations during Kharif 2006 and seed production in an area of 100 ha during second year LST.

6.0 LARGE SCALE TRIALS IN CENTRAL ZONE

6.1 Permission for 2nd year large scale trials and seed production of transgenic cotton hybrids JK-99 containing Cry 1Ac gene (EVENT 1) by M/s J K Agri Genetics Ltd

1. The Committee considered the request for second year LST with JK-99 containing Cry 1Ac gene (event 1) in the Central zone. It was noted that the field trials have been monitored by MEC. The MEC has recommended these for commercial release subject to completion of procedural requirement.

The second year LST is being requested because the procedural requirement of two year ICAR trials has not been completed.

2. In view of the above stated facts, the GEAC approved the conduct of second year LST with JK-99 in the Central zone at 60 locations during Kharif 2006 and seed production in an area of 100 ha during second year LST.

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