

Decisions taken in the 79th Meeting of the Genetic Engineering Approval Committee held on 8.8.2007

The 79th meeting of the Genetically Engineering Approval Committee (GEAC) was held on 8.8.2007 at 11.00 AM in Room No. 623 in the Ministry of Environment and Forests under the Chairmanship of Sh. B. S. Parsheera, Additional Secretary, MoEF and Chairman, GEAC.

1.0 Consideration of Proposals related to Pharmaceuticals

A. Pharmaceuticals

1.1 Permission for import to conduct Phase III Clinical trials with r-adenovirus p 53 (rAdp53) in the treatment for newly diagnosed unresectable squamous cell carcinoma of head and neck from China by M/s Intas Biopharmaceuticals Ltd.

1.0 The Committee considered the request to import r-adenovirus p 53 (rAdp53) manufactured by Shenzhen SiBiono Gene Tech Co.,Ltd. China. for conduct of Phase III Clinical trials in India. The Committee noted that the product has been in commercial use for a period of 2 years in China. However, no PMS data has been submitted for assessing the safety and efficacy of the product. It was also noted that the product has not been approved by USFDA.

3.0 Since, Gencicine is the first injection to be used as drug and approved in China to be used for gene therapy for the treatment of cancer; it was decided to await comments of the experts before the proposal is considered for phase – III clinical trials in India. Accordingly, decision on the proposal was deferred.

1.2 Permission for import of Indi Age Super L from M/s. Genecor International , The Netherland by M/s Lumis Bipotech Pvt. Ltd.

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1.3 Permission for import of from M/s. Genecor International , The Netherland by M/s Lumis Bipotech Pvt. Ltd.

1.0 The Committee considered the proposals of M/s Lumis Biotech Pvt. Ltd. at agenda item 1.2 and 1.3 for import of Indi Age Super L and Indi Age Super GX Plus, a concentrated Cellulase enzyme produced by M/s Genecor International the Netherlands.

2.0 After detailed deliberations, the Committee decided to approve the request for import of Indi Age Super L and Indi Age Super GX Plus, for further value addition and subsequent export subject to the following conditions:

- a) The DGFT would monitor the quantity of import and subsequent export after value addition.
- b) The DGFT should direct the Company to follow 'Rules 1989' and obtain approval of GEAC prior to such imports in future.

1.4 Permission for manufacture of indigenously developed Human Immunodeficiency Viral (HIV) antigens p24, gp120 and gp41 for diagnostic kit development by M/s. Sudershan Biotech Ltd.

1.0 The Committee noted that comments from Expert Members are awaited and accordingly decided to take up the matter in the next GEAC meeting. Decision on the proposal was therefore, deferred.

1.5 Permission for import and conduct of phase II clinical trials of Chimerivaxtm –JE in children of descending age from USA by M/s Quintiles Research (India) Pvt. Ltd.

1.0 The Committee noted that the import of Chimerivaxtm —JE from USA to conduct phase II clinical trials of Chimerivaxtm —JE vaccine in children of descending age was approved in the 66th meeting of GEAC held on 2.5.2006. The Applicant was directed, in the first instance to conduct Phase II trials in the highest age group i.e. >5 and > 10 years of age. After completing the trials in children of the highest group, the applicant was advised to submit the clinical trials data and approach GEAC for conducting trials in the lower age group of children along with the safety data, information on adverse events if any and the rescue operations during the trials.

2.0 The Committee noted that comments from Expert Members are awaited and accordingly decided to take up the matter in the next GEAC meeting. Decision on the proposal was therefore, deferred.

2.0 Consideration of proposals for Transgenic crops

1.0 Before initiating discussion on the agenda items, the Member-Secretary, GEAC informed the Committee that the RCGM in its meetings held on 28.6.2007 and 24.7.2007 has recommended 1 proposal for MLRT with transgenic brinjal, 5 proposals for pollen flow/ biosafety studies with Bt brinjal, transgenic cotton, Bt okra, Bt rice and Bt tomato and 4 proposals for Strip trials with transgenic rice, transgenic groundnut, Bt cotton and Bt brinjal expressing new gene event. RCGM has also recommended 52 proposals for MLRT and SAU trials, 8 proposals for strip trials and 31 proposals for experimental seed production with Bt cotton expressing approved gene events. In accordance with the Hon'ble SC order dated 1.5.2006 the proposals recommended by RCGM as listed in Agenda items 5 to 10 and Agenda item 12 are placed for consideration of the GEAC.

2.0 The Committee also deliberated on the following issues:

A. Status of PIL in WP 260/2005 & IA 4/2006 filed by M/s Aruna Rodrigues vs UOI.

1.0 The Committee noted that the Ministry of Environment and Forests, jointly with DBT and MoA has filed an application for vacating/amending the following directions issued by the Hon'ble Supreme Court vide Order dated 8.5.2007 based on the recommendations of the Sub Committee.

1. An isolation distance of 200 m would be maintained during field trials.
2. Prior to bringing out the GM material with new gene/event from the green house for conduct of open field trial the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination .

2.0 It was informed that the matter came up for hearing on 1.8.2007 and was deferred by six weeks at the request of the Petitioners seeking additional time for filing the rejoinder The Hon'ble

Supreme Court has also directed the GEAC to post the biosafety data on the MoEF/DBT website. The Hon'ble SC has also permitted to file this information in CD-Rom.

3.0 In light of the above submissions, the Committee opined that all Applicants may be directed to comply with the above requirements until a favorable relief is granted by the Hon'ble Supreme Court.

B. Recommendations of the Sub Committee to assess the implications of the Hon'ble SC directions dated 8.5.2007.

1.0 The Committee noted that in the 76th GEAC meeting, held on 11.5.2007, a Sub Committee under the Chairmanship of Dr. B. M. Khadi, Director, CICR, Nagpur was constituted to examine the implications of the Hon'ble Supreme Court Order dated 8.5.2007 and advise the GEAC on the measures to be taken to ensure its compliance. The meeting of the Sub-Committee was held on 24.7.2007.

2.0 The Committee considered the following recommendations of the Sub-Committee:

a. Recommendation of the Sub Committee with respect to uniform isolation distance of 200 m to be maintained during GM crop field trials:

i. Scientifically, a uniform isolation distance is not tenable as the nature of the pollen flow and level of contamination depends on the biology of the crop and the host environment in which it is being cultivated. Therefore, each crop would need unique isolation distance. It is recommended that the isolation distance prescribed under the Indian Minimum Seed Certification Standards manual may be followed. In addition to the prescribed isolation distance, additional biosafety measures as indicated in **table 1 (Column 7)** may be prescribed on a case to case basis. The combination of physical and biological containment measures prescribed by the regulatory agencies is adequate to maintain the genetic purity at the highest possible levels.

Table 1: Adequate biosafety during the conduct of field trials for GM crops

	Crop	Nature of pollination	Pollinating agent (s)	Minimum isolation (m) prescribed in IMSCS@	Isolation (m) recommended by the Sub Committee	Additional biosafety measures recommended by the Sub Committee
1.	Cotton	Often cross pollinated	Insects	50	200	-
2.	Rice	Self	Wind	200	200	Physical barrier around the crop of ~ 700 gauge thick polythene or similar material upto 2 m height.
3.	Okra*	Cross	Insects	500	500*	*Trial to be conducted under the insect proof net covering

4.	Groundnut	Self	-	3	10	-
5.	Potato	Self	-	5 (tubers) 50 (TPS)	100	-
6.	Tomato	Self	Solitary bee, thrips	200	200	As in Okra
7.	Brinjal	Self	Insects	300	300	As in Okra
8.	Castor	Cross	Wind	600 (Hybrid) 1000 (Female)	1000	-
9.	Cauliflower & Cabbage	Cross	Bees	1600	200	To be harvested at curd maturity stage
10	Mustard & Rapeseed (Oilseed brassicac)	Self Cross	Bees	100	50-100	-.

*Okra being an insect-pollinated crop, netting may restrict insect movement to some extent and hence, affect agronomic yield. To minimize its adverse effect on insect behaviour, height of the net cover should be at least 1-1.5 m above the plant height. No such problem is envisaged in tomato and brinjal which are self pollinated crops.

@Indian Minimum Seed Certification Standards (1988), Central Seed Certification Board, DAC, Ministry of Agriculture, GOI, New Delhi

Compendium of proceedings of Technical Committee of CSCB (1986-2004). (Revisions and Amendments).

Central Seed Certification Board, DAC, Min. of Agriculture, GOI, New Delhi.

b. Recommendation of the Sub Committee with respect to submission of a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.

- i. In view of the stringent guidelines of maintaining scientifically prescribed isolation distance in seed production standards (which, for several crops, is more than the 200 m isolation distance as prescribed by the Hon'ble Supreme Court) and additional biosafety measures prescribed during field testing of GM crops, the possibility of contamination is rare (**refer table 1**). Therefore, the requirement for a validated protocol of 0.01% LOD may be dispensed with.
- ii. Prior to the commercial release/ export requirements, the LOD may be decided at levels that are practical to use, compatible with the acceptable thresholds that may be defined for labeling purposes and are based on the technical aspects of the analytical methods available in the international laboratories and the genome size of the crop. Thus the arbitrary requirement for provision of a detection method with an LOD of 0.01% at the time of field trial is scientifically not justified and may be dispensed with.

3.0 Some of the Expert members opined that recommendation of the Sub Committee stipulating 200 m isolation distance in respect of cotton crop is not clear as the Seed Certification Standard mandates a distance of only 50 m. Also there is a need to provide a clear justification for stipulating a larger /lower isolation distance than that prescribed under the Seed Certification Standards. The GEAC requested the Sub Committee to reconsider the recommendations in respect of isolation distance in light of the discussions held in the GEAC meeting. In case of any modification, the

Committee authorized the Chairman, GEAC to review the recommendations and if required file an application for amending the submissions made by the GoI for vacating / modifying the Hon'ble SC order dated 8.5.2007.

C. The recommendations of RCGM:

1.0 The Committee noted that the following recommendations/decisions taken by RCGM in the meeting held on 1.6.2007 has been endorsed by the GEAC in the meeting held on 22.6.2007.

- i. MLRT for new events should not be conducted in the farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms, long leased land or at the SAU/ICAR institutions.
- ii. In accordance with the Hon'ble Supreme Court direction an isolation distance of 200 m should be maintained.
- iii. Strip trials, for new events should be undertaken by the Company in their own premises/ research farms. An isolation distance of 200 m should be maintained as per the Hon'ble Supreme Court direction.
- iv. Applicant should generate complete biosafety data along with MLRT.
- v. The applicant should submit a validated event specific test protocol before undertaking the trials.
- vi. For all new events applicants to include plant parts, such as leaves/shoot/bolls in addition to seeds in the animal feeding studies for biosafety evaluation in the wake of certain reports indicating adverse effects of the leaves/shoot/bolls on animals.
- vii. MLRT may be conducted in minimum 1 location and maximum at 2 locations in each State.

2.0 One of the expert members opined that condition No. iv above may not be made mandatory during the MLRT as many of the research institutions developing transgenic crops are in the process of selecting the best gene event during the MLRT. Therefore, it may not be practical to conduct the biosafety data in respect of all new gene events. The Committee while agreeing with the above suggestion also reiterated that complete biosafety data should be submitted before the proposal is considered for large scale field trials. Therefore it is up to the institution to decide for which gene event biosafety studies should be initiated and at what stage. The Committee was also of the view that in case of crops where the isolation distance prescribed under the Seed Certification Standard is higher than the 200 m prescribed by the Hon'ble Supreme Court, the isolation distance prescribed by the Seed Certification Standard shall be made applicable.

3.0 Consideration of proposals for Multi Location Research Trials of GM new crops/ events

3.1 Permission to conduct Multi location field trials (MLRT) of four transgenic Bt brinjal namely Co2-Bt, MDU1-Bt, KKM1-Bt and PLR1-Bt containing *cry1Ac* gene (EE1 event) at five locations i.e Horticultural College and Research Institute, Coimbatore, Horticultural College and Research Institute, Periyakulam, Agricultural College and Research Institute, Madurai, Agricultural College and Research Institute, Killikulam and Vegetable Research Station, Palur during June-September 2007 and January-April 2008 to evaluate their Agronomic performance and efficacy in controlling fruit and shoot borer and the effect on beneficial insects. by Tamil Nadu Agricultural University (TNAU), Coimbatore .

1.0 The Committee considered the proposal at agenda 3.1 in light of the above deliberations with respect to Hon'ble Supreme Court directions dated 8.5.2007, recommendations of the Sub Committee with respect to isolation distance and LOD of 0.01% and recommendation of RCGM. The Committee noted that the isolation distance prescribed by the Seed Certification Standards is 300 m for brinjal

2.0 After detailed deliberations, the GEAC approved the proposal for MLRT of four transgenic Bt brinjal developed by TNAU subject to the following conditions:

- i. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
- ii. The applicant should submit to the RCGM/GEAC an event specific test protocol of 0.01% duly validated/ verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.
- iii. An isolation distance of minimum 300 m shall be maintained.
- iv. The MLRT shall not be conducted in farmers' fields. MLRT should be undertaken by the Companies/Institutions either in its own premises, research farms, long leased land (a minimum of three years lease) or at the SAU/ICAR institutions.

3.0 The Committee further noted that number of locations for MLRT may be restricted to 2 locations as per the decision taken by the RCGM and GEAC. The Committee authorized DBT to seek necessary clarification from TNAU before according approval for MLRT.

4.0 Consideration of proposals for Pollen flow/biosafety studies of GM new crops/ events

- 4.1 Permission to conduct Pollen flow studies of Bt brinjal containing *cry* 1F gene in confined field conditions at two different agro climatic conditions at Jalna and Varanasi in company's own farm and to generate efficacy data of Bt brinjal against targets insects. by Bejo Sheetal Seeds Pvt. Ltd, Jalna.
- 4.2 Permission to generate BG-II RRF cotton plant material in confined field conditions during Rabi 2007 to conduct biosafety studies by M/s. Maharashtra Hybrid Seeds Company Ltd., Mumbai.
- 4.3 Permission to generate Bt okra plant material in confined field conditions during Rabi 2007 to conduct biosafety studies by M/s. Maharashtra Hybrid Seeds Company Ltd., Mumbai.
- 4.4 Permission to conduct pollen flow studies from marker free transgenic Bt rice expressing *cry* 2Ab gene in confined field conditions by M/s. Maharashtra Hybrid Seeds Company Ltd., Mumbai.
- 4.5 Permission to conduct pollen flow studies from marker free transgenic Bt tomato expressing *cry* 2Ab gene in confined field conditions by M/s. Maharashtra Hybrid Seeds Company Ltd., Mumbai.

1.0 The Committee considered the proposals at agenda 4.1 to 4.5 and noted that RCGM in its meeting held on 28.6.2007 has recommended the **Pollen flow studies with Bt brinjal, Bt rice and Bt tomato and generation of plant material** with Bt cotton and Bt okra subject to the following conditions-

- i. Pollen flow studies / generation of plant material shall be undertaken by the Companies/Institutions either in their own premises / research farms.
- ii. In accordance with the Hon'ble Supreme Court direction an isolation distance of 200 m should be maintained.

- iii. The applicant should submit a validated event specific test protocol before undertaking the trials.

2.0 As regards items 6.2 and 6.3 it was informed that RCGM has set up a Sub Committees to develop crop specific biosafety protocols including those for toxicity and allergenicity studies. Further, ICMR guidelines for the Safety Assessment of Foods derived from Genetically Modified / Recombinant DNA Plants is also under consideration. Since the report of the Sub Committees' are expected within 4 – 6 weeks, whether the Applicant may initiate biosafety studies at this stage was discussed. After detailed deliberations it was decided that the Applicant may follow the protocols for biosafety studies as per the existing guidelines. Additional studies / addendum to the existing protocols may be prescribed as and when the report of the Sub Committees' is accepted by the RCGM / GEAC. During the deliberations, one of the expert member suggested that the Sub Committee may also decide the number of locations for pollen flow studies based on the different agro climatic zone.

3.0 After detailed deliberations, the Committee approved the proposals at agenda item 4.1 to 4.5 for **Pollen flow studies with Bt brinjal, Bt rice and Bt tomato and generation of plant material** with Bt cotton and Bt okra subject to the following conditions-

- i. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
- ii. The applicant should submit to the RCGM/GEAC an event specific test protocol of 0.01% LOD duly validated/ verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.
- iii. An isolation distance of minimum 200 m shall be maintained. In cases where the Seed Standards Certification mandates a larger isolation distance, the same shall be maintained (300 m for brinjal, 200 m for rice , tomato and cotton).
- iv. The pollen flow / generation of plant material shall be undertaken by the Companies/Institutions in their own premises or research farms only.

5.0 Consideration of proposals for strip trial of GM crops expressing new genes/events

- 5.1 Permission to conduct **strip trials** of transgenic rice containing truncated synthetic *cry1Ac* gene to evaluate bioefficacy of transgenic integration events in elite rice lines under fields conditions during Kharif (June – July) 2007 by M/s. Metahelix Life Sciences, Bangalore.
- 5.2 Permission for repeating the **contained field experiments** for evaluation of transgenic groundnut plants vars JL-24 carrying the chitinase gene from rice (Rchit) against the aflatoxin-producing *Aspergillus flavus* and other fungal pathogens. by ICRISAT, Patancheru, A.P.
- 5.3 Permission for conducting **strip trial and seed increase** of 7 Bt cotton hybrids containing *cry* 1EC gene Event24) along with the commercialized *cry1Ac* gene (Event-1) namely JKCH-99 Bt, JK- Durga Bt, JK-Varun Bt, JK-Ishwar Bt, JK-Indra Bt, JKCH-226 Bt and JKCH-666 Bt at two location viz. JKAL- Own breeding farm in Central and South zones during Kharif 2007 by JK Agri Genetics, Hyderabad.

1.0 The Committee considered the proposals at agenda 5.1 to 5.3 and noted that RCGM in its meeting held on 28.6.2007 has recommended the **strip trial** with transgenic rice, transgenic groundnut and Bt cotton subject to the standard conditions.

2.0 After detailed deliberations, the Committee approved the proposals at agenda item 5.1 to 5.3 for strip trials with transgenic rice, transgenic ground and Bt cotton subject to the following conditions:

- i. The applicant should submit to the RCGM/GEAC the name of the Lead Scientist responsible for the trials before undertaking the trials.
- ii. The applicant should submit to the RCGM/GEAC an event specific test protocol of 0.01% LOD duly validated/ verified by ICGEB, New Delhi / NBRI, Lucknow or any other accredited laboratory before undertaking the trials.
- iii. An isolation distance of minimum 200 m shall be maintained. In cases where the Seed Standards Certification mandates a larger isolation distance, the same shall be maintained.
- iv. The strip trials shall not be conducted in farmers' fields. Strip trials should be undertaken by the Companies/Institutions in their own premises or research farms.

6.0 Consideration of proposals for Multi Location Research Trials (MLRT) / SAU of Bt-cotton expressing approved genes/events

- 6.1** Permission to conduct **Multi- location trials and SAU trials** of 4 Bt cotton hybrids namely ACH-4, ACH-5, ACH-6 and Ajeet Paramveer-1 containing *cry1Ac and cry 2Ab genes* (MON 15985) at 6 locations viz. Guntur, Adilabad, Warangal, Coimbatore/Peramballur, Salem, Davangere/Haveri in **South Zone** during Kharif 2007 by Ajeet Seeds Ltd., Aurangabad.
- 6.2** Permission for conducting **Multi- location trials and SAU trials** of 4 Bt cotton hybrids namely ACH-1, ACH-2, ACH-3 and ACH-177-1 containing *cry1Ac gene* (MON 531) at 8 locations viz. Jalgaon, Aurangabad Yeotmal, Bhuranpur , Khandwa, Khargone, Baroda and Bharuch in **Central Zone** during Kharif 2007. by Ajeet Seeds Ltd., Aurangabad
- 6.3** Permission to conduct **Multi- location trials and SAU trials** of 4 Bt cotton hybrids namely ACH-1, ACH-2, ACH-3 and ACH-133-1 containing *cry1Ac gene* (MON 531) at 6 locations viz. Guntur, Adilabad, Warangal, Coimbatore/Peramballur, Salem, Davangere/Haveri in **South Zone** during Kharif 2007 by Ajeet Seeds Ltd., Aurangabad
- 6.4** Permission for conducting **Multi- location trials and SAU trials** of 4 Bt cotton hybrids (HxB) namely ACH-4, ACH-5, ACH-6 and Ajeet Paramveer-1 containing *cry1Ac and cry2Ab genes* (MON 15985) at 8 locations viz. Jalgaon, Aurangabad Yeotmal, Bhuranpur , Khandwa, Khargone, Baroda and Bharuch in **Central Zone** during Kharif 2007. by Ajeet Seeds Ltd., Aurangabad.
- 6.5** Permission to conduct **Multi- location trials and SAU trials** of 2 Bt cotton hybrids (HXB) namely ACH-901-1 and ACH-907-1 containing *cry1Ac gene* (MON 531) at 6 locations viz. Jalgaon, Padegaon, Ratlam, Banswara in **Central zone** and Mysore/Dharwad and Coimbatore in **South zone** during Kharif 2007 and their experimental seed production on 40 hectare each. by Ajeet Seeds Ltd., Aurangabad
- 6.6** Permission to conduct **Multi location trials (RCGM/ICAR)** for three hybrids namely ABCH 3083 Bt, ABCH-3483 Bt, and ABCH 1857 Bt, containing *cry1Ac gene* (Event MON 531) at 14 locations viz. Aurangabad, Akola, Jalgaon, Jalna, Badwani, Khandwa, Baroda and Anand in **Central Zone** and Mahboobnager, Guntur, Hyderabad, Coimbatore, Dharwad and Haveri in **South Zone** during Kharif 2007. by Amar Bio-Tech Ltd., Hyderabad.

- 6.7** Permission to conduct **Multi location trials** (RCGM/ICAR) of four hybrids namely ABCH 1299 Bt, ABCH-2099 Bt, ABCH 4899 Bt and ABCH 7399 Bt containing *cry1Ac* & *cry2Ab* genes (MON 15985) at 16 locations viz. Aurangabad, Akola, Jalgaon, Jalna, Badwani, Burhanpur, Baroda and Anand in **Central Zone** and Mahboobnager, Guntur, Hyderabad, Coimbatore, Dharwad and Haveri in **South Zone** during Kharif 2007. by Amar Bio-Tech Ltd., Hyderabad to obtain
- 6.8** Permission to conduct replicated **Multi location trials** of 3 cotton hybrids namely Jai BGII, Ankur 3028 BGII and Ankur 3034 BGII containing *cryX* (*cry1Ac* & *cry2Ab*) gene (MON 15985) at 6 locations viz. Warangal, Guntur, Belgaum, Davangere, Trichy, Villupuram in **South Zone** during Kharif 2007-08. by Ankur Seeds Pvt. Ltd., Nagpur
- 6.9** Permission to conduct replicated **Multi- location trials** of 2 cotton hybrids namely Ankur HB 2108 BGII, Ankur HB 2110 BGII containing *cryX* (*cry1Ac* & *cry2Ab* gene (MON 15985) at 6 locations viz. Warangal, Guntur, Belgaum, Davangere, Trichy, Villupuram in the **South Zone** during Kharif 2007-08. by Ankur Seeds Pvt. Ltd., Nagpur
- 6.10** Permission to conduct replicated **Multi- location trials, SAU trials and Seed production** of 3 Bt cotton hybrids namely Ankur 3032 Bt, Ankur 1262 Bt and Ankur 3034 Bt containing *cry1Ac* gene (MON 531) at 8 locations viz. Gandhinagar, Rajkot, Baroda, Bharuch, Khargone, Nagpur, Aurangabad and Dhuli in **Central Zone** 2007-08. by Ankur Seeds Pvt. Ltd., Nagpur.
- 6.11** Permission to conduct **Multi location field trials (MLT)** of Bt cotton hybrid namely GK205 Bt containing *cry1Ac* gene (MON 531) at 6 locations A.P (Warangal, Adilabad and Guntur), Karnataka (Bellary and Haveri) and Tamilnadu (Salem) in South zone during Kharif 2007. The applicant has also requested to recommend SAU trials of Bt cotton hybrid GK205 Bt in South zone ANGRAU, Hyderabad, UAS, Dharwad and TNAU, Coimbatore. by M/s. Ganga Kaveri Seeds Pvt. Ltd., Hyderabad.
- 6.12** Permission to conduct **Multi location field trials (MLT)** of two Bt cotton hybrids namely GK207 Bt and GK209 Bt containing *cry1Ac* gene (MON 531) at 8 locations Maharashtra (Aurangabad, Jalgaon, Parbhani, Akola), Gujrat (Sabarkanta and Rajkot) and M.P. (Khargaon, Badwani) in Central during Kharif 2007. The applicant has also requested to recommend SAU trials of two Bt cotton hybrids GK207 Bt and GK209 Bt in Central zone PKV, Akola, MPKV, Rahuri, MAU, Parbhani, GAU, Dantiwada, JAU, Junagarh, AAU, Anand and JNKVV, Jabalpur. by M/s. Ganga Kaveri Seeds Pvt. Ltd., Hyderabad.
- 6.13** Permission to conduct **Multi location field trials (MLT)** of two Bt cotton hybrids (HXH) namely GBCH07 Bt and GBCH09 Bt containing fusion gene *cry1Ab-Ac* at 8 locations Maharashtra (Aurangabad, Jalgaon, Yeotmal, Akola), Gujrat (Baroda and Rajkot) and M.P. (Khargaon, Khandwa) in Central and 6 locations A.P (Warangal and Guntur), Karnataka (Ranebennur and Davangere) and Tamilnadu (Coimbatore and Salem) in South zones during Kharif 2007 by M/s. Green Gold Seeds Ltd., Aurangabad.
- 6.14** Permission to conduct **controlled open field trials** of 4 transgenic cotton hybrids containing *cry1Ac* (Event1) (Set-1 HXH) namely JKCH-2245 Bt, JKCH-2022 Bt, JKCH-2301 Bt, JK-Ishwar Bt at 8 locations viz. Jalgaon, Jalna, Aurangabad, Yeotmal, Rajkot, Himmatnagar, Vadodara, Khandwa, Ratlam in Central zone by JK Agri Genetics, Hyderabad.
- 6.15** Permission to conduct **controlled open field trial** of 4 transgenic cotton hybrids containing *cry1Ac* (Event1) (Set-1 HXH) namely JKCH-2253 Bt, JKCH-2246 Bt, JKCH-1305 Bt, JKCH-2004Bt at 6 locations viz. Warangal, Guntur, Ranga Reddy, Dharwad/Haveri, Davangere and Salem in South zone. by JK Agri Genetics, Hyderabad.
- 6.16** Permission to conduct **Multi Location Fields Trial (MLTs)** on **three (HXB)** Bt cotton hybrids namely KDCHH -407 BGI, KDCHH -5402 BGI and KDCHH -5409 BGI containing *cry1Ac* gene MON 531 to assess the tolerance against Bollworm complex infestation at eight

locations Sangali, Akola, Jalna, Jalgaon, Dhamnod Ratlam, Junagadh, and Jamnagar in **Central zone** during Kharif 2007 by Krishidhan Seeds Ltd., Attur .

- 6.17** Application submitted by Krishidhan Seeds Ltd., Attur to obtain permission to conduct **Multi Location Fields Trial (MLTs)** on **four (HXH)** Bt cotton hybrids namely KDCHH –507 BGI, KDCHH –619 BGI, KDCHH –553 BGI, KDCHH –665 BGI. containing *cry1Ac* gene MON 531 to assess the tolerance against Bollworm complex infestation at seven locations Akola, Jalna, Jalgaon, Dhamnod Sanawad, Junagadh, and Jamnagar in **Central zone** during Kharif 2007.
- 6.18** Permission to conduct **Multi Location Fields Trial (MLTs)** on **3** BG II cotton hybrids KDCHH –616 BGII, , KDCHH –658 BGII, KDCHH-9821 BG II containing *cry1Ac* and *cry 2Ab* gene MON 15985 to assess the tolerance against Bollworm complex infestation at eight locations Akola, Jalna, Jalgaon, Dhamnod Sanawad, Junagadh, and Jamnagar in **Central zone** during Kharif 2007 Application submitted by Krishidhan Seeds Ltd., Attur.
- 6.19** Permission to conduct **Multi Location Fields Trial (MLTs)** on **five (HXH)** Bt cotton hybrids namely KDCHH –507 BGI, KDCHH –619 BGI, KDCHH –553 BGI, KDCHH –665 BGI and KDCHH-9821 BG I containing *cry1Ac* gene MON 531 to assess the tolerance against Bollworm complex infestation at six locations Warangal, Guntur/Medak, Dharwad, Haveri, Attur, Terambalur in **South zone** during Kharif 2007. by Krishidhan Seeds Ltd., Attur.
- 6.20** Permission to conduct **Multi Location Fields Trial (MLTs)** on **five** BG II cotton hybrids KDCHH –616 BGII, KDCHH –641 BGII, KDCHH –658 BGII, KDCHH –541 BGII., KDCHH-9821 BG II containing *cry1Ac* and *cry 2Ab* gene MON 15985 to assess the tolerance against Bollworm complex infestation at six locations Warangal, Guntur/Medak, Dharwad, Haveri, Attur, Perambalur at **South zone**. by Krishidhan Seeds Ltd., Attur.
- 6.21** Permission to conduct **Multi Location Research Trial (MLRT)** of 9 test hybrids namely EGCH 1426 B2, EGCH 5 B2, EGCH 63 B2, EGCH 1447 B2, EGCH 128 B2, EGCH 73 B2, Brahma BGII, Sudrashan BGII and EGCH 1423 BGII containing *cry1Ac* and *cry2Ab* genes (MON 15985) at seven locations viz. Akola, Aurangabad, Jalna, Khandwa, Khargoan, Bhavnagar and Rajkot in **Central zone** during Kharif 2007. by Monsanto India Limited, Mumbai.
- 6.22** Permission to conduct **Multi Location Research Trial(MLRT)** on 7 test cotton hybrids namely EGCH 5 B2, EGCH 63 B2, EGCH 72 B2, EGCH 128 B2, EGCH 1426 B2, EGCH 1447 B2 and EGCH 1448 B2 containing *cry1Ac* and *cry2Ab* genes(MON 15985) at six locations viz. Warangal, Hyderabad, Dharwad, Haveri, Perambalur and Salem in **South zone** during Kharif 2007 by Monsanto India Limited, Mumbai
- 6.23** Permission to conduct **Multi location field trials / SAU/ICAR trials** in contained open fields for five transgenic cotton hybrids namely NSPL-432 Bt(HXH), NSPL-9 Bt (HXH), NSPL-666 Bt(HXH) NSPL-63 Bt (HXB), NSPL-603 Bt (HXH) containing *cry1Ac* gene (MON 531) at locations for (HXH) Aurangabad, Parbhani, Jalgaon, Yavatmal, Badwani, Bhuranpur, Rajkot, Bhavnagar, and for (HXB) Jalgaon, Parbhani, Aurangabad, Ratlam, Jabua, Rajkot in **Central zone** during Kharif 2007. Nandi Seeds Pvt. Ltd., Mahabubnagar
- 6.24** Permission to conduct **Multi location field trials / SAU / ICAR trials** in contained open fields for five transgenic cotton hybrids namely NSPL-432 Bt(HXH), NSPL-9 Bt (HXH), NSPL-666 Bt(HXH) NSPL-63 Bt (HXB), NSPL-603 Bt (HXH) containing *cry1Ac* gene (MON 531) at locations for (HXH) Mahaboobnagar, Guntur, Khammam, Haveri, Davangere, Palani, and for (HXB) Mahaboobnagar, Guntur, Khammam, Mysore, Dharwad, Palani in **South zone**.
- 6.25** Permission to conduct **Multi location field trials** of 5 Bt cotton hybrids NSPL-432 BGII, NSPL-423BG-II, NSPL-666 BG-II, NSPL-333BG-II and NSPL-9BGII containing *cry1Ac* and *cry2Ab* genes (MON 15985) at 8 locations namely Aurangabad, Parbhani, Jalgaon, Yavatmaql, Badwani, Bhuranpur, Rajkot and Bhavnagar. by Nandi Seeds Pvt. Ltd., Mahabubnagar

- 6.26** Permission to conduct **Multi location field trials** of 5 Bt cotton hybrids NSPL-432 BGII, NSPL-423BG-II, NSPL-666 BG-II, NSPL-333BG-II and NSPL-36BGII containing *cry1Ac* and *cry2Ab* genes (MON 15985) at 6 locations namely Mahbubnagar, Guntur, Khammam, Haveri, Davangere and Palani in **South Zone**. by Nandi Seeds Pvt. Ltd., Mahabubnagar.
- 6.27** Permission to conduct **Multi location field trials / RCGM trials** of 3 Bt cotton hybrids namely ACH-1010 Bt, ACH-1051 Bt, and ACH-1052 Bt containing GFM *cry1A* gene at 8 locations in **Central zone** during Kharif 2007 by Nandi Seeds Pvt. Ltd., Mahabubnagar.
- 6.28** Permission to conduct **Multi-locations field trials** of 4 Bt cotton hybrids namely NCS 859 Bt 2, NCS 860 Bt 2, NCS 861 Bt 2, NCS 862 Bt 2 containing *cry1Ac* and *cry 2Ab* gene to assess their resistance to Lepidopteran pests of cotton and evaluate their agronomic performance at 6 locations Adilabad, Warangal, Guntur, Dharwad, Haveri, Attur in **South** and 8 locations Bhavnagar, Rajkot, Khargaon, Badwani, Aurangabad, Jalgaon, Nanded, Yavatmal in **Central zones** Kharif 2007. by Nuziveedu Seeds Ltd., Secunderabad.
- 6.29** Permission for conducting **Multi-locations field trials** of 5 Bt cotton hybrids namely NCS 906 Bt, NCS 907 Bt, NCS 908 Bt, NCS 909 Bt and NCS 910 Bt. containing *cry1A(c)* gene (MON 531) of Mahyco-MMB to assess their resistance to Lepidopteran pests of cotton and evaluate their agronomic performance at 14 locations viz. Bhavnagar, Aurangabad, Jalgaon, Rajkot, Nanded, Khargone, Badwani, Yavatmal in **Central Zone** and Adilabad, Warangal, Guntur, Dharwad, Haveri, Attur in **South Zone** during Kharif 2007 by Nuziveedu Seeds Ltd., Secunderabad.
- 6.30** Permission to conduct **Multi-locations field trials** of 4 hybrids namely PCH 115 Bt 2, PCH 881 Bt 2, PCH 882 Bt 2, PCH 883 Bt 2 containing *cry1Ac* and *cry 2Ab* genes of Mahyco-MMB to assess their resistance to Lepidopteran pests of cotton and evaluate their agronomic performance at eight locations at Bhavnagar, Baroda, Aurangabad, Rajkot, Jalgaon, Khargone, Nanded, Badwani, Yavatmal in **Central Zone** and six locations Adilabad, Warangal, Guntur, Dharwad, Haveri, Attur in **South zone** during Kharif 2007 by Prabhat Agri Biotech Ltd., Hyderabad.
- 6.31** Permission for conducting **Multi-locations field trials** of 5 hybrids namely PCH 404 Bt, PCH 405 Bt, PCH 407 Bt, PCH 408 Bt and PCH 409 Bt containing *cry1A(c)* gene of Mahyco-MMB to assess their resistance to Lepidopteran pests of cotton and evaluate their agronomic performance at 14 locations at Bhavnagar, Aurangabad, Rajkot, Jalgaon, Khargone, Nanded, Badwani, Yavatmal in **Central Zone** and Adilabad, Warangal, Guntur, Dharwad, Haveri and Attur in **South Zone** during Kharif 2007. by Prabhat Agri Biotech Ltd., Hyderabad.
- 6.32** Permission to conduct **Multi location field trials (MLTs)** of **seven** Bt cotton hybrids namely PRCH-251 BG II, PRCH-304 BG II, PRCH-305 BG II, PRCH-306 BG II, PRCH-331 BG II, PRCH-333 BG II, PRCH-213 BG II with *cry1Ac* and *cry2Ab* genes (MON 15985 event) to assess their resistance to bollworm complex infestation particularly *Helicoverpa armigera* at 8 locations Yeotmal, Nanded, Parbhani, Jalgaon, Ahmedabad, Junagadh, Khargaon, Khandwa in **Central zone** and 6 locations Guntur, Warangal, Bhainsa, Parigi, Dharwad, Davangere in **South zone**. by Parvardhan Seeds Pvt. Ltd., Hyderabad.
- 6.33** Permission to conduct **Multi Location Field Trials (MLTs)** and **SAU trials** on **3** (H x B) Bt cotton hybrids namely PRCHB-402 Bt BG I, PRCHB-403 Bt BG I and PRCHB-405 Bt BG I containing *cry1Ac* gene (MON 531 event) to assess their resistance to bollworm complex infestation particularly *Helicoverpa armigera* at eight locations (Parbhani, Jalgaon, Junagadh, Surat, Ahmedabad, Ratlam, Dhar and Jabua) in **Central** and six locations (Guntur, Warangal, Parigi, Mysore, Belgaum and Dharwad) in **South zones** during Kharif 2007-08. by Parvardhan Seeds Pvt. Ltd., Hyderabad.

- 6.34** Permission to conduct **Multi location testing** of 10 Bt cotton F1 hybrids namely TPHCN07-001 to TPHCN07-010 containing GFM cry1a gene at 8 locations viz. Aurangabad, Jalna, Jalgaon, Yeotmal, Khandwa, Ratlam, Rajkot and Himmatnagar in **Central zone** during kharif 2007 and to assess the comparative performance of the first hybrids under different conditions of **Central zone**. by RJ Biotech, Aurangabad.
- 6.35** Permission to conduct **Multi Location Field Trials (MLTs)** on Bt cotton hybrids namely SWCH-1 and SWCH-2 containing *cry1Ac* and *cry2Ab* gene (MON 15985) to assess the tolerance against bollworm complex infestation at eight locations i.e. Nagpur, Yavatmal, Nanded, Jalgaon, Khandwa, Khargaon, Baroda, Bhavnagar in **Central zone** during Kharif 2007. by SeedWorks India Pvt. Ltd., Hyderabad.
- 6.36** Permission to conduct **Multi Location Field Trials (MLTs)** on Bt cotton hybrids namely SWCH-1 and SWCH-2 containing *cry1Ac* and *cry2Ab* gene (MON 15985) to assess the tolerance against bollworm complex infestation at six locations i.e. Hyderabad, Warangal, Guntur, Kallakurchi, Hubli, Davangere in **South zone** during Kharif 2007 by SeedWorks India Pvt. Ltd., Hyderabad
- 6.37** Permission to conduct **Multi Location Field Trials (MLTs)** on **five** Bt cotton hybrids namely SWCH-4314, SWCH-4322, SWCH-4324, SWCH-4428, SWCH-4531 containing *cry1Ac* gene (MON 531 event) at six locations i.e. Hyderabad, Guntur, Warangal, Hubli, Davangere, Kallakurchi and **SAU trials** at two locations per university i.e. Acharya NG Ranga Agricultural University, Tamil Nadu Agricultural University, University of Agricultural Sciences, Dharwad in **South zone** during Kharif 2007 by SeedWorks India Pvt. Ltd., Hyderabad .
- 6.38** Permission to conduct **Multi Location Field Trials (MLTs)** on **five** Bt cotton hybrids namely SWCH-4314, SWCH-4322, SWCH-4324, SWCH-4428, SWCH-4531 containing *cry1Ac* gene (MON 531 event) at eight locations i.e. Nagpur, Yavatmal, Nanded, Jalgaon, Khandwa, Khargaon, Baroda, Bhavnagar and **SAU trials** at two locations per university viz. Marathwada Agricultural University, Jawaharlal Nehru Krishi Viswavidyalya, Junagadh Agricultural University in **Central zone** during Kharif 2007. by SeedWorks India Pvt. Ltd., Hyderabad.
- 6.39** Permission to conduct **Multi location Trials (MLTs)** of **five** Tulasi Bt transgenic cotton hybrids namely Tulasi-45 Bt, Tulasi-7 Bt, Tulasi-118 Bt, Tulasi-36 Bt and Tulasi-127 Bt carrying *cry1Ac* (MON 531) and of **five** Bt transgenic cotton hybrids namely Tulasi-7 BGII , Tulasi-127 BGII , Tulasi-45 BGII , Tulasi-36 BGII and Tulasi-21 BGII containing *cryX* (*cry1Ac* and *cry2Ab*) gene (MON 15985) at eight locations Jalgaon, Yeotmal, Jalna, Parbhani, Bhuranpur, Khargaon, Rajkot, Baroda in **Central zone** during Kharif 2007 and for assessing the gene efficacy of 10 Tulasi Bt cotton hybrids in contained open field. by Tulasi Seeds Pvt. Ltd., Guntur
- 6.40** Permission to conduct **Multi location Trials (MLTs) and to assess the gene efficacy** of **four** Tulasi Bt transgenic cotton hybrids namely Tulasi-45 Bt, Tulasi-7 Bt, Tulasi-118 Bt and Tulasi-127 Bt carrying *cry1Ac* (MON 531), **six** Bt transgenic cotton hybrids namely Tulasi-7 BGII, Tulasi-45 BGII, Tulasi-36 BGII (HxH) and Tulasi-333 BGII, Tulasi-666 BGII, Tulasi-999 BGII (HxB) containing *cryX* (*cry1Ac* and *cry2Ab*) gene (MON 15985) at six locations viz. Guntur, Warangal, Ranga Reddy, Dharwad, Haveri and in **South zone** during Kharif 2007. by Tulasi Seeds Pvt. Ltd., Guntur.
- 6.41** Permission to conduct **multi location field trials** on 9 Bt cotton hybrids i.e. UPLHH-3 Bt, UPLHH-7 Bt, UPLHH-8 Bt, UPLHH-9 Bt, UPLHH-11 Bt, UPLHH-168 Bt, UPLHH-264 Bt, UPLHH-265 Bt and UPLHH-189 Bt containing cry1Ab-Ac genes (GFM *Cry1A*) in 8 locations viz. Khargone, Khandwa, Gandhinagar, Rajkot, Jalna, Jalgaon, Yavatmal and Parbhani in **Central zone** and 6 locations viz. Guntur, Khammam, Coimbatore, Attur, Dharwad and Haveri in **South zones** during Kharif 2007. by M/s. Uniphos Seeds and Bio-Genetics, Mumbai .

- 6.42** Permission to conduct contained **multi-location research** field trials (MLRT) of 2 Bt cotton hybrids (HXB) namely VBCHB1201 and VBCHB1203 containing *cry1Ac* (MON531) gene at 4 locations (Jalgaon (Maharashtra), Khargaon, Khandwa, Ratlam (M.P.) in **Central zone** and 3 locations (Dharwad, Mysore (Karnatka) Attur (T.N)) in **South zone** during Kharif 2007. The applicant had also requested for permission to conduct **SAU trials** on the same hybrids in central and south zones and **seed production** in the area of 100 hectares for each hybrid. by M/s Vibha Agrotech Ltd., Hyderabad.
- 6.43** Permission to conduct **Multi location field trials / RCGM trials** with 5 BGII cotton hybrids namely VCH-634 (BG-II), VCH-639 (BG-II), VCH-641 (BG-II) VCH-650 and VCH-653 (BG-II) containing *cryX* (*cry1Ac* & *cry2Ab*) gene (MON 15985 event) at 8 locations [Gujarat (Ahmedabad, Junagadh) Maharashtra (Jalgaon, Aurangabad, Yavatmal, Parbhani) M.P. (Khargaone, Badwani) in **Central zone** during Kharif 2007. by Vikki Agrotech Pvt. Ltd., Hyderabad .
- 6.44** Permission to conduct **Multi location field trials / RCGM trials** of 2 Bt cotton hybrids namely VCH-208 Bt and VCH-225 Bt (Bhagya Bt) containing *cry1Ac* (MON 531 event) at 8 locations [Gujarat (Ahmedabad, Junagadh) Maharashtra (Jalgaon, Aurangabad, Yavatmal, Parbhani) M.P. (Khargaone, Badwani) in **Central zone** during Kharif 2007. The applicant has also requested State Agricultural **Universities (SAUs)** MAU, MPKV, JAU and JMKVV of Central zone to organize field trials as per RCGM recommendations. by Vikki Agrotech Pvt. Ltd., Hyderabad.
- 6.45** Permission to conduct **Multi location field trials / RCGM trials** with 2 Bt cotton hybrids namely VCH-208 Bt and VCH-225 Bt (Bhagya Bt) containing *cry1Ac* genes (MON 531 event) at six locations Andhra Pradesh (Warangal, Guntur, Adilabad), Karnataka (Haveri, Davangeri), Tamil Nadu (Coimbatore) in **South zone** during Kharif 2007. The applicant has also requested State Agricultural Universities (SAUs) ANGRAU (Guntur), ANGRAU (Warangal), UAS (Dharwad), TNAU (Coimbatore) of South zone to organize field trials as per RCGM recommendations. by Vikki Agrotech Pvt. Ltd., Hyderabad.
- 6.46** Permission to conduct **Multi location field trials / RCGM trials** with 5 BGII cotton hybrids namely VCH-608 BGII, VCH-610 BGII, VCH-614 BGII, VCH-615 BGII and VCH-616 BGII containing *cryX* (*cry1Ac* and *cry2Ab*) gene (MON 15985 event) at 6 locations Andhra Pradesh (Warangal, Guntur, Adilabad), Karnataka (Haveri, Davangeri), Tamil Nadu (Coimbatore) in **South zone** during Kharif 2007. by Vikki Agrotech Pvt. Ltd., Hyderabad.
- 6.47** Permission to conduct **Multi location field trials** of 5 Bt cotton hybrids namely VICH-101 Bt (BG-II), VICH-102 Bt (BG-II), VICH-103 Bt (BG-II), VICH-106 Bt (BG-II) and VICH-107 Bt (BG-II) containing *cry1Ac* and *cry2Ab* genes (MON 15985 event) at 8 locations [Gujarat (Gandhinagar, Kheda, Rajkot) Maharashtra (Jalgaon, Aurangabad, Bhuldhana) M.P. (Khargaone, Khandwa) in **Central zone** during Kharif 2007. by Vikram Seeds Ltd., Ahmedabad.
- 6.48** Permission to conduct **Multi location field trials** of 4 cotton hybrids namely VICH-101 Bt (BG-II), VICH-102 Bt (BG-II), VICH-104 Bt (BG-II) VICH-109 Bt (BG-II) containing *cry1Ac* and *cry2Ab* genes (MON 15985 event) at 6 locations [Andhra Pradesh (Warangal, Karimnagar, Mahabubnagar, Guntur), Karnataka (Haveri, Dharwad) in **South zone** during Kharif 2007 by Vikram seeds Ltd., Ahmedabad
- 6.49** Permission to conduct **multi location trial/RCGM Trial of** six Bt hybrids (F1) namely YRCH-4 Bt, YRCH-9 Bt, YRCH-13 Bt, YRCH-31 Bt, YRCH-45 Bt and YRCH-54 Bt containing GFM *cry1A* gene of the 30 Bt hybrids prepared under an agreement signed with GTL and Yashoda Seeds at 8 locations in **Central Zone** and 6 locations in **South Zone** during Kharif 2007. by Yashoda Hybrid Seeds Pvt. Ltd., Wardha

6.50 Permission to test **six** Bt hybrids (F1) namely ZCH-50066 Bt, ZCH-50106 Bt, ZCH-50110 Bt, ZCH-50147 Bt, ZCH-50164 and ZCH-5007 Bt, in **Multi location trials** of **Central zone** at eight locations in Central zone Zuari Seeds Ltd., Bangalore.

6.51 Permission to test **five** Bt hybrids (F1) namely ZCH-50066 Bt, ZCH-50097 Bt, ZCH - 50106 Bt, ZCH-50111 Bt and ZCH-50164 Bt in **Multi location trials** of **South zone** at six locations (Guntur, Adilabad, Dharwad, Haveri, Coimbatore and Salem). by Zuari Seeds Ltd., Bangalore.

1.0 The Committee considered the proposal at agenda 6.1 to 6.51 and noted that RCGM in its meeting held on 28.6.2007 has recommended multi-locational field trials with Bt cotton hybrids expressing approved four gene events *cry 1Ac* (MON-531 event), "GFM *Cry 1A*", *cry 1Ac & cry 2Ab* (Mon 15985) and *cry 1Ac* (Event -1) developed by the several companies. The condition stipulated by the Supreme Court in respect of isolation distance and submission of validated event specific test protocol before undertaking the trials would not be applicable in these cases. However the condition regarding nomination of a lead Scientist who would be responsible for the trials would be applicable. The Committee was also of the view that the sowing season for the North and Central zones being over, trials with Bt cotton hybrids expressing approved gene events may be considered only for the South zone.

2.0 In accordance with the recommendations of the sub-Committee report on the Bt cotton and related issues, RCGM has taken into consideration the following information while recommending the hybrids for multi locational Research trials.

- a. Confirmation of gene event by molecular analysis
- b. Protein (*Cry 1Ac*) expression data from greenhouse / station strip trials
- c. Morphological characterization using DUS descriptors
- d. Bio efficacy data generated in laboratory conditions
- e. Authorization / NOC from the technology provider

3.0 It was further reiterated that in respect of Bt cotton expressing *cry 1Ac* (MON 531 event) all hybrids approved for MLRT may also be approved for SAU trials in tandem in accordance with the Sub Committee report on Bt cotton and related issues. During the deliberations the need for continued case by case regulation of Bt cotton expressing *cry 1Ac* (MON 531 event) which has been commercialized and is extensively being cultivated in majority of the cotton growing area was discussed. It was further noted that the PPV-FR Act further mandates compulsory registration which would take into consideration the case verification criteria mentioned in para 2 above. It was therefore, decided to set up a Sub Committee comprising of the following members:

- | | | |
|------|---|------------------|
| i. | Dr. B. M. Khadi , Director, CICR, Nagpur | Chairman |
| ii. | Dr. P. Anand Kumar , Head, NRCPB New Delhi. | Member |
| iii. | Dr. M. Uday Kumar , University of Agricultural Science, Bangalore. | Member |
| iv. | Dr. Rakesh Tuli , Director, NBRI, Lucknow | Member |
| v. | Dr. N. Gopalakrishnan , Project Coordinator, AICCIP | Member |
| vi. | Dr. K. K. Tripathi , Adviser, DBT | Member |
| vii. | Dr. R. Warriar , Director, MoEF | Member-Secretary |

4.0 The terms of reference of the Committee would include

- a) To review the need for continued case by case regulation of Bt cotton expressing *cry 1Ac* (MON 531 event) and implication of de regulation if any.
- b) Rationalization of the Zones based on the agro climatic conditions
- c) Recommendation regarding the suitability for release of Bt cotton in other cotton growing states.

5.0 After detailed deliberations, the Committee approved the proposals at agenda 6.1 to 6.51 for MLRT only for the South zone subject to the following conditions:

- i. The applicant should give a written information to obtain approval of the Gram Panchayat before undertaking the trials in farmers field, a copy of which would be provided to RCGM/GEAC, State govt authorities and Director of Research of the SAUs.
- ii. The applicant should submit to the RCGM/GEAC, the State govt. officials, the State/District wise details of locations (area, village, name of farmers etc) before undertaking the trials.

7.0 Consideration of proposals for strip trials of Bt cotton Expressing approved genes/events

7.1 Permission to evaluate of 12 newly developed Bt. Cotton F1 hybrids containing fusion gene (*cry* 1Ab-1Ac) and limited quantity hybrid seeds production of 12 Bt cotton hybrids in contained condition during Kharif 2007. by Safal Seeds & Biotech Ltd., Aurangabad

7.2 Permission to conduct **strip trial** of 40 F1 Bt cotton hybrids namely TPHCN07-011 to TPHCN07-050 containing fusion gene (*cry* 1Ab-1Ac) under contained field condition at RJ Biotech's Research farm, Farola. by RJ Biotech, Aurangabad .

7.3 Permission to conduct **strip trials** with **115** transgenic Bt cotton hybrids containing stacked genes *cry*1Ac & *cry*2Ab genes (MON 15985 event) to asses their resistance to bollworm complex including *Spodoptera* and other insects and performance in **South zone** during Kharif 2007 by Vikki Agrotech Pvt. Ltd., Hyderabad .

1.0 The Committee considered the proposals at agenda 7.1 to 7.3 and noted that RCGM in its meeting held on 28.6.2007 has recommended the strip trials with Bt cotton hybrids expressing approved gene events namely "GFM *Cry 1A*" and *cry 1AC and cry 2Ab* (Mon 15985) developed by several companies.

2.0 In accordance with the recommendations of the sub-Committee report on the Bt cotton and related issues, RCGM has taken into consideration the following information while recommending the hybrids for Strip trials-

- i. Confirmation of gene event by molecular analysis
- ii. Protein (*Cry 1Ac*) expression data from greenhouse / station strip trials
- iii. Morphological characterization using DUS descriptors
- iv. Bio efficacy data generated in laboratory conditions
- v. Authorization / NOC from the technology provider

3.0 After detailed deliberations the Committee approved the proposals at agenda 7.1 to 7.3 only for the South Zone subject to the following conditions:

- a. The applicant should give a written information to obtain approval of the Gram Panchayat before undertaking the trials in farmers field.
- b. The applicant should submit to the RCGM/GEAC, the State/District wise details of locations (area, village, name of farmers etc) before undertaking the trials.

8.0 Consideration of proposals for Experimental Seed Production of Bt cotton expressing approved genes/events

8.1 Permission for half acre **experimental seed production** of two cotton hybrids namely Ankur HB 2108 BGII, Ankur HB 2110 BGII containing *cry*X(*cry*1Ac & *cry*2Ab gene (MON

- 15985) at own research farm in **South Zone** during Kharif 2007. by Ankur Seeds Pvt. Ltd., Nagpur
- 8.2** Permission for **Seed production** of 3 Bt cotton hybrids namely Ankur 3032 Bt, Ankur 1262 Bt and Ankur 3034 Bt containing *cry1Ac* gene (MON 531) at 8 locations viz. Gandhinagar, Rajkot, Baroda, Bharuch, Khargone, Nagpur, Aurangabad and Dhuli in **Central Zone** 2007-08. by Ankur Seeds Pvt. Ltd., Nagpur
 - 8.3** Permission for conducting half acre **seed production** of two Bt cotton hybrids (HXH) namely GBCH07 Bt and GBCH09 Bt containing fusion gene *cry1Ab- Ac* (GFM *cry1A*) at their own research farm during Kharif 2007. by M/s. Green Gold Seeds Ltd., Aurangabad
 - 8.4** Permission to produce hybrids seeds of 11 BGII cotton hybrids namely EGCH 5 B2, EGCH 63 B2, EGCH 72 B2, EGCH 73 B2, EGCH 128 B2, EGCH 1426 B2, EGCH 1447 B2 and EGCH 1448 B2, Brahma BGII, Sudarshan BGII and EGCH 1423 BGII containing *cry1Ac* and *cry2Ab* genes(MON 15985) in one location at Research Station, Kallakal, Hyderabad by Monsanto India Limited, Mumbai .
 - 8.5** Permission for seed production **five** Bt cotton hybrids namely NSPL-432 Bt (HxH), NSPL-9 Bt (HxH), NSPL-666 Bt (HxH), NSPL-63 Bt (HxB) and NSPL-603 (HxB) containing *cry 1Ac* gene (MON 531) by M/s Nandi Seed Pvt. Ltd., Mahboobnager .
 - 8.6** Permission for **experimental seed production** of 3 Bt cotton hybrids namely ACH-1010 Bt, ACH-1051 Bt, and ACH-1052 Bt containing GFM *cry1A* gene in an area of 0.5 acre for each hybrid at Botad Research Farm owned by the organization. by Navkar Hybrid Seeds Pvt. Ltd., Ahmedabad
 - 8.7** Permission for **experimental seed production** of **four** hybrids namely NCS 859 Bt 2, NCS 860 Bt 2, NCS 861 Bt 2, NCS 862 Bt 2 containing *cry1Ac* and *cry 2Ab* gene in **Central** and **South zones** at their own research farm during Kharif 2007. by Nuziveedu Seeds Ltd., Secunderabad
 - 8.8** Permission **for seed production** of 5 Bt cotton hybrids namely NCS 906 Bt, NCS 907 Bt, NCS 908 Bt, NCS 909 Bt and NCS 910 Bt. containing *cry1A(c)* gene (MON 531) at 14 locations viz. Bhavnagar, Aurangabad, Jalgaon, Rajkot, Nanded, Khargone, Badwani, Yavatmal in **Central Zone** and Adilabad, Warangal, Guntur, Dharwad, Haveri, Attur in **South Zone** during Kharif 2007.
 - 8.9** Permission for **seed production** of 2 Bt cotton hybrids namely NCHB 995 Bt and NCHB 996 Bt containing *cry1A(c)* gene at 14 locations viz. Bhavnagar, Aurangabad, Jalgaon, Rajkot, Ratlam, Khargone, Jabua, Yavatmal in **Central Zone** and Dharwad, Mysore, Rasipuram, Tirupattur Haveri, Attur in **South Zone** Kharif 2007. by Nuziveedu Seeds Ltd., Secunderabad.
 - 8.10** Permission for **seed production** of 4 hybrids namely PCH 115 Bt 2, PCH 881 Bt 2, PCH 882 Bt 2, PCH 883 Bt 2 containing *cry1Ac* and *cry 2Ab* genes at their own research farm in **Central** and **South zones** during Kharif 2007. by Prabhat Agri Biotech Ltd., Hyderabad.
 - 8.11** Permission for **seed production** of 5 hybrids namely PCH 404 Bt, PCH 405 Bt, PCH 407 Bt, PCH 408 Bt and PCH 409 Bt containing *cry1A(c)* gene at 14 locations at Bhavnagar, Aurangabad, Rajkot, Jalgaon, Khargone, Nanded, Badwani, Yavatmal in **Central Zone** and Adilabad, Warangal, Guntur, Dharwad, Haveri and Attur in **South Zone** during Kharif 2007. by Prabhat Agri Biotech Ltd., Hyderabad
 - 8.12** Permission for conducting **experimental seeds increase** of **three (HXB)** Bt hybrids PRCHB-402 Bt BG I, PRCHB-403 Bt BG I and PRCHB-405 Bt BG I with *cry1Ac* gene (MON

531 event) in **Central** and **South** zones at their own research farm during Kharif 2007-08. by Parvardhan Seeds Pvt. Ltd., Hyderabad.

- 8.13** Permission to **experimental seed production** of **seven** transgenic cotton hybrids namely PRCH-251 BG II, PRCH-304 BG II, PRCH-305 BG II, PRCH-306 BG II, PRCH-331 BG II, PRCH-333 BGII and PRCH-213 BGII for Central and South Zones at their own research farm during Kharif 2007. by Parvardhan Seeds Pvt. Ltd., Hyderabad.
- 8.14** Permission for **seed increase** of the parental lines and generation larger quantity of 10 Bt cotton F1 hybrids namely TPHCN07-001 to TPHCN07-010 containing GFM cry1a gene at 8 locations viz. Aurangabad, Jalna, Jalgaon, Yeotmal, Khandwa, Ratlam, Rajkot and Himmatnagar in **Central zone** during Kharif 2007. by RJ Biotech, Aurangabad.
- 8.15** Permission for **seed production** each of five Bt cotton hybrids (HXH) namely SWCH-4314, SWCH-4322, SWCH-4324, SWCH-4428, SWCH-4531 containing *cry1Ac* gene (MON 531 event) during Kharif 2007. by SeedWorks India Pvt. Ltd., Hyderabad.
- 8.16** Permission for experimental **seed production** of two Bt cotton hybrids namely SWCH-1 Bt and SWCH-2 Bt containing *cry1Ac* and *cry2Ab* gene (MON 15985) in an area of 0.5 acres each during Kharif 2007, by SeedWorks India Pvt. Ltd., Hyderabad.
- 8.17** Permission for **seed production** of two Bt cotton hybrids namely VBCHB1201 and VBCHB1203 in **Central** and **South Zone** containing *cry1Ac* (MON531) gene during Kharif 2007. by M/s Vibha Agrotech Ltd., Hyderabad
- 8.18** Permission for **experimental seeds increase** of 5 BGII cotton hybrids viz. VCH-634 (BG-II), VCH-639 (BG-II), VCH-641 (BG-II) VCH-650 (BG-II) VCH-653 (BG-II) containing *cryX(cry1Ac & cry2Ab)* gene (MON 15985 event) proposed for MLT / RCGM trials in **Central zone** during Kharif 2007. by Vikki Agrotech Pvt. Ltd., Hyderabad.
- 8.19** Permission for **experimental seeds increase** of 5 BGII cotton hybrids namely VCH-608 BGII, VCH-610 BGII, VCH-614 BGII , VCH-615 BGII and VCH-616 BGII containing *cryX (cry1Ac and cry2Ab)* gene (MON 15985 event) in **South zone** during Kharif 2007. The seeds will be utilized for large scale field trials and ICAR / SAU trials, in open field conditions during Kharif- 2008 by Vikki Agrotech Pvt. Ltd., Hyderabad.
- 8.20** Permission for **experimental seeds increase** of 28 Bollgard II Bt cotton hybrids namely SO7H984, VCH 621, VCH 6281,SO7H701,SO7H703, SO7H705, SO7H709, SO7H717, SO7H721, SO7H723, SO7H742, SO7H748, SO7H753, SO7H775, SO7H787, SO7H798, SO7H802, SO7H821, SO7H822, SO7H825, SO7H827, SO7H828, SO7H835, SO7H843, SO7H844, SO7H851,SO7H852,SO7H984, with stacked gene *cryX s(cry1Ac & cry2Ab)* gene (MON 15985 event) during Kharif 2007 at polyhouse at R & D farm, Nandigama, Hyderabad. The seeds will be utilized for large scale field trials and ICAR / SAU trials, in open field conditions during Kharif- 2008. by Vikki Agrotech Pvt. Ltd., Hyderabad.
- 8.21** Application submitted by Vikki Agrotech Pvt. Ltd., Hyderabad to conduct **seeds increase** of 100 ha. each of two Bt hybrids namely VCH-208 Bt and BCH-225 Bt (Bhagya Bt) containing *cry1Ac* (MON531) proposed for MLT/RCGM trials in **Central** and **South zones** during Kharif 2007.
- 8.22** Permission for **experimental seeds production** of 7 Bt cotton hybrids namely VICH-101 (BG-II), VICH-102 (BG-II), VICH-103 (BG-II), VICH-104 (BG-II), , VICH-106 (BG-II), VICH-107 (BG-II), VICH-109 (BG-II) containing *cry1Ac* and *cry2Ab* genes (MON 15985 event) required for large scales field trials and ICAR / SAU trials in open field conditions during Kharif 2007 by Vikram seeds Ltd., Ahmedabad .

- 8.23** Permission to carry out the hybrid **experimental seed production** activity in an area of about 0.5 acres per hybrid for **eight** Bt hybrids (F1) ZCH-50097 Bt ,ZCH-50110 Bt ZCH-5007 Bt and ZCH-50147 Bt, ZCH-50066 Bt, ZCH-50106 Bt, ZCH-50164Bt and ZCH-50111 Bt during Kharif 2007 by Zuari Seeds Ltd., Bangalore to obtain.
- 8.24** Permission for seed production of 5 Bt cotton hybrids NSPL-432 BGII, NSPL-423BG-II, NSPL-666 BG-II, NSPL-333BG-II and NSPL-9BGII containing *cry1Ac* and *cry2Ab* genes (MON 15985) at their own research farm in **Central Zone** during Kharif 2007. by Nandi Seeds Pvt. Ltd., Mahabubnagar.
- 8.25** Permission to conduct **Multi location field trials** of 5 Bt cotton hybrids NSPL-432 BGII, NSPL-423BG-II, NSPL-666 BG-II, NSPL-333BG-II and NSPL-36BGII containing *cry1Ac* and *cry2Ab* genes (MON 15985) at their own research farm in **South Zone** during Kharif 2007 by Nandi Seeds Pvt. Ltd., Mahabubnagar.
- 8.26** Permission for conducting seed production 6 Bt cotton hybrids namely ACH-1, ACH-2, ACH-3, ACH-177-1, ACH-901-1 and ACH-907 containing *cry1Ac gene* (MON 531) at 8 locations viz. Jalgaon, Aurangabad Yeotmal, Bhuranpur , Khandwa, Khargone, Baroda and Bharuch in **Central Zone** and at 6 locations viz. Guntur, Adilabad, Warangal, Coimbatore/Peramballur, Salem, Davangere/Haveri in **South Zone** during Kharif 2007 Ajeet Seeds Ltd., Aurangabad.
- 8.27** Permission for **experimental seed production** of 4 Bt cotton hybrids namely ACH-4, ACH-5, ACH-6 and Ajeet Paramveer-1 (all HxB) containing *cry1Ac and cry2Ab genes* (MON 15985) at their own research farms (2) in **Central** and **South Zones** during Kharif 2007 by Ajeet Seeds Ltd., Aurangabad .
- 8.28** Permission for **seed production** of **eight** Bt cotton hybrids namely KDCHH –507 BGI, KDCHH –619 BGI, KDCHH –553 BGI, KDCHH –665 BGI, KDCHH-9821 BGI, KDCHH –407 BGI, KDCHH –5402 BGI and KDCHH –5409 BGI containing *cry1Ac gene* MON 531 at 14 locations as per MLRT in **Central** and **South zones** during Kharif 2007 by Krishidhan Seeds Ltd., Attur .
- 8.29** Permission for **experimental seed production** of **five** BG II cotton hybrids KDCHH –616 BGII, KDCHH –641 BGII, KDCHH –658 BGII, KDCHH –541 BGII., KDCHH-9821 BG II containing *cry1Ac* and *cry 2Ab* gene MON 15985 in **Central** and **South zones** in their own research farms during Kharif 2007. by Krishidhan Seeds Ltd., Attur
- 8.30** Permission to conduct **Experimental Seed Production** of 10 Bt cotton hybrids namely BN bt, NHH-44Bt, DBtH1, DBtH2, DBtH3, DBtH4, DBtH5, DBtH6, DBtH7 and DBtH8 at two locations at their own research farms by CICR, Nagpur.

The Committee approved experimental seed production as per the prevailing regulatory practice. In case of seed production with Bt cotton expressing *cry 1Ac* (MON-531 event), it was reiterated that no specific approval for seed production is required. The applicant can undertake seed production subject to submission of an undertaking to RCGM that the seed production shall not be diverted for any other purpose without the approval of RCGM.

9.0 Other Items

9.1 Consideration of the Report of the Expert Committee on Bt brinjal expressing *Cry 1Ac* gene developed by M/s Mahyco.

1.0 The Committee noted that the request of M/s Mahyco for conduct of LST with Bt brinjal expressing *cry 1Ac* gene tolerant to fruit and shoot borer was considered by the GEAC in the meeting held on 1.6.2006 wherein it was decided to post the biosafety data on Bt brinjal on MoEF website for

inviting public comments. Subsequently, an Expert Committee was constituted with the following terms of reference:

- a) To evaluate comments received from the various stakeholders vis-à-vis the biosafety data generated by the Company and available scientific /technical data/literature from studies conducted by various national and international institutions.
- b) Suggest additional studies (if any) to be conducted.
- c) To evaluate the adequacy of the protocol proposed for LST and recommend additional safeguards (if any).
- d) Recommend protocol for socio economic studies.
- e) Any other recommendation on related aspects.

2.0 The Member Secretary, GEAC informed that the Expert Committee on Bt Brinjal has finalized its recommendations in the meeting held on 3.7.2007. She further briefed the Committee on the deliberations held in the Expert Committee meetings and placed the report of the Expert Committee for consideration of the GEAC.

3.0 The GEAC noted the following observations/ recommendations made by the Expert Committee:

"A. *The Committee concluded that the biosafety data generated by the Applicant is in accordance with the protocol and procedures stipulated by the regulatory agency. However, Bt brinjal being the first GM food crop to be released in India and the first to be released globally, the Committee was of the view that a cautious step by step approach needs to be taken. While the data generated by the Applicant concludes that the Bt brinjal is safe and equivalent to its non Bt counterpart, the Committee was of the opinion that more independent studies especially with respect to toxicity assay in NABL accredited laboratories may be required to re-affirm the findings made in the earlier studies. The Committee further opined that the short term data generated on the environmental safety and socio economic aspects needs to be further substantiated with additional trials / tests to explicitly conclude the benefits from Bt brinjal and superiority of the technology with respect to existing technologies especially with respect to methods for pest management and pesticide reduction.*

The Committee is, therefore, of the opinion that large scale field trials may be allowed subject to the conditions mentioned below:

a) *All field trials should be conducted in the research farm under the control of ICAR/IIVR. The trial should be carried out under the direct supervision of Director, IIVR.*

b) *All field trials should strictly comply with the Hon'ble Supreme Court direction dated 8.5.2007 which directs:*

- *All trials should have a lead scientist's name with contact details who would be responsible for all aspects of the trials including regulatory requirements.*
- *An isolation distance of 200 m would be maintained during field trials.*
- *Prior to bringing out the GM material from the green house for conduct of open field trial the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.*

B. *The Committee further recommends conduct of the following studies during large scale trials:*

a. *Field trials for assessing the environmental safety and agronomic advantage of Bt brinjal needs to be repeated at a minimum of 10-11 locations to represent different agro climatic zones for two seasons. The protocols for the trials would be finalized by RCGM in consultation with Director, IIVR.*

- b. *The pollen flow would be recorded during the field trials every 10 m up to 200 m in one trial plot at a minimum of 6 locations representing different agro climatic zones for a period of two years. The pollen flow study should be conducted with a minimum of around 100 standing plants, planted at an interval of 75x50 cm spacing.*
- c. *The field trials should include at a minimum of one location (at IIVR, Varanasi) to assess the extent of cross ability of Bt brinjal (*Solanum melongena*) with *S. incanum*. The trial should also record the findings with respect to weediness and invasiveness of *S. incanum* containing transgene..*
- d. *As per the directions issued by RCGM baseline susceptibility data needs to be generated for at least three pests - Fruit and Shoot borer (*Leucinodes orbonalis*), Gram caterpillar/fruit borer (*Helicoverpa armigera*) and Stem borer (*Euzophera perticella*), over a minimum of two years (two seasons). The Committee noted that baseline susceptibility data for stem borer have not been generated. The Committee advised that the same may be conducted during the two year field trials.*
- e. *The Cry1Ac protein expression levels were assessed every 30 days and not every 15 days as prescribed by RCGM through the crop cycle. The Committee recommends the study be repeated in accordance with the procedure prescribed by RCGM.*
- f. *Soil impact assessment study should include tests on the counts related to Rhizobium in the soil of Bt and normal plots and for the presence/absence of Cry1Ac protein at different depths (up to one metre) in the soil at one location. The changes in fertility and impact on next crop may also be recorded. In other words carry over effects of residues of Bt brinjal should be investigated.*
- g. *Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits may be included as an additional parameter and this study may be undertaken at CFTRI.*
- h. *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.*
- i. *The Food / Feed Safety assessment should include foliage toxicity study in Goats.*
- j. *The skin sensitization test of transgenic material in guinea pigs as laid down in the DBT guidelines has not been taken up. The Committee recommended the study may be conducted.*
- k. *Additional toxicity / allergenicity / compositional / nutritional studies as recommended by Director, NIN after examining the raw data on food and feed safety generated by the Applicant.*
- l. *Detailed socio economic study as prescribed by a three member Sub Committee comprising of Dr. S. Parasuraman, Director, TISS, Mumbai, Dr. M.N. Murthy, Director, IEG and Dr. Mathura Rai, Director, IIVR, Varanasi.*
- m. *Analysis of fruit dry matter to determine differences in yield from the agronomic trials in respect of Bt and check entries.*

Results from all studies must be reviewed along with the socio economic study to decide on the introduction of Bt brinjal in India."

4.0 The GEAC also considered the response of the Expert Committee to the stakeholder comments. After detailed deliberation, the GEAC was of the view that the Expert Committee has examined the proposal and concerns expressed by the Public in depth. The GEAC, therefore, accepted the recommendations of the Expert Committee and approved the large scale field trials at 11 locations with Bt brinjal for generation of additional biosafety data subject to the following conditions:

- i. The large scale field trials will be conducted in the ICAR Institutional farms under the direct supervision of Director, IIVR, Varanasi.
- ii. The protocols for the field trials shall be designed by Director, IIVR, Varanasi.
- iii. Socio economic studies as prescribed by the three members Committee shall be conducted.
- iv. Additional toxicity / allergenicity/ nutritional studies, if any, as recommended by Director, NIN, shall be conducted.
- v. Additional studies prescribed by the Expert Committee shall be conducted.

- vi. All field trials shall be in accordance with the Hon'ble Supreme Court directions dated 8.5.2007.

9.2 Permission for Large Scale Trials and seed production of cotton hybrids expressing new gene even in North, Central and South Zones developed by Central Institute for Cotton Research, Nagpur.

1.0 The above proposal was considered by the GEAC in its meeting held on 22.6.2007 wherein the Applicant was directed to complete the biosafety studies in the first instance and also submit a validated event specific test protocol at LOD of at least 0.01%.

2.0 The Member Secretary, GEAC informed the Committee that the applicant vide communication dated 6.8.2007 has requested the GEAC to reconsider the above requirement taking into consideration that the Bt cotton has been developed by CICR, Nagpur a public institutions under ICAR system. An early release of the product would be highly beneficial to the farmers especially in the competitive market. Further, Director, CICR assured that all large scale trials would be conducted in the Institutional farm and safety precautions such as isolation distance along with physical and biological barrier shall be followed to ensure there will be no contamination of the neighboring Bt cotton fields.

3.0 He informed the Committee that the feed studies with goat has been initiated and will be concluded within 3 weeks. However, the feeding studies on cows can be initiated only after approval of CPCSEA is obtained. In this regard, Director, NDRI has approached Chairman, CPCSEA for use of transgenic material for biosafety test on cow. He requested Chairman, GEAC who is also the Chairperson of CPCSEA to expedite the above approval.

4.0 He also informed that the Institute after careful consideration of all the technical aspects related to LOD of at least 0.01% has concluded that it will not be possible to meet the requirement in respect of cotton crop. He, therefore, requested the Committee to relax the requirement of the test protocol and permit large scale field trials at least in the South zone on the following grounds:

- i. The Hon'ble Supreme Court directions have proved to be a major set back in the research and development of transgenic crops in the public institutions with limited resources and funding. The sowing season for the North and Central zones is already over and the institute has lost a period of one year for conducting trials in this area. Since, the next date of hearing of the PIL in the Hon'ble Supreme Court is scheduled for September, 2007; the testing period for the South Zone will also be over.
- ii. The MoEF / DBT have filed an application for vacating/ amending the directions regarding submission of test protocol of 0.01% LOD. The submissions made in the application clearly indicate that a uniform LOD of 0.01% cannot be applicable for all crops.
- iii. The material developed by CICR, Nagpur has already come out of the green house and has been tested under field conditions during Kharif, 2006.

5.0 The Committee deliberated at length the request made by CICR. The Committee was of the view that the submissions made by Director, CICR merits consideration and full support needs to be provided to facilitate release of transgenic cotton from public institutions. At the same time, it was agreed that any relaxation on the Hon'ble SC directions at this stage would tantamount to 'Contempt of Court' which is avoidable under all circumstances. The Committee advised CICR and ICAR to file an application for relief immediately. The Chairman, GEAC requested Member Secretary, GEAC and RCGM to provide all support to CICR, Nagpur for filing the application for relief in the Hon'ble Supreme Court.

10. Other items with the permission of the Chair.

- 10.1 Permission to conduct confined **Multi Location Research Trials (MLRT)** on **7 Bt** cotton hybrids namely UPLHH-4Bt, UPLHH-6Bt, UPLHH-10Bt, UPLHH-12Bt, UPLHH-13Bt, UPLHH-271Bt and UPLHH-275Bt containing *cry1Ab*-Ac genes (*GFM cry1A*) at 14 locations i.e. Khargone, Khandwa, Boroda, Rajkot, Gandhinagar, Yavatmal and Aurangabad in Central zone and Guntur, Khammam, Coimbatore, Attur, Dharwad and Haveri in South zone during Kharif 2007 by M/s. Uniphos Enterprises Ltd., Mumbai.
- 10.2 Permission to conduct **Confined Limited Research Trial (Strip trial)** on 11 Bt Brinjal F1 hybrids namely BSS- 5171, BSS- 5172, BSS- 5173, BSS- 5174, BSS- 5175, BSS- 5176, BSS- 5177, BSS- 5178, BSS- 5179, BSS- 5180, BSS- 5181 containing *cry1Fa* gene at Sarwadi Farm, Jalna. to evaluate their resistance against larval infestation of Brinjal fruit and shoot borer by M/s. Bejo Sheetal Seeds Pvt. Ltd., Jalna.
- 10.3 Permission to conduct **Confined Limited Research Trial (Strip trial)** on **90 Bt** cotton hybrids (HXH) containing *GFM cry1A* gene at North, Central (Aurangabad, Ankleshwar) and South (Khammam) zones to carry out the research work on transfer of the *GFM cry1A* synthetic fusion gene into elite non-Bt cotton lines and development of Bt hybrids in greenhouse and open fields during Kharif 2007 by M/s. Uniphos Enterprises Ltd., Mumbai.
- 10.4 Permission to conduct **Confined Limited Research Trial (strip trial)** on **7 BG I (HXH) cotton hybrids** i.e. 1. NAMCOT 404 BG I, 2. NAMCOT 416 BG I, 3. NAMCOT 418 BG I, 4. NAMCOT 419 BG I, 5. NAMCOT 421 BG I, 6. NAMCOT 422 BG I and 7. NAMCOT 423 BG I, **2 BG I (HXB) hybrids** i.e. NAMCOT 801 BG I and 7. NAMCOT 802 BG I containing **cry1Ac gene (MON531)** and **7 BG II (HXH) hybrids** i.e. 1. NAMCOT 603 BG II, 2. NAMCOT 604 BG II, 3. NAMCOT 605 BG II, 4. NAMCOT 614 BG II, 5. NAMCOT 615 BG II, 6. NAMCOT 616 BG II and 7. NAMCOT 617 BG II hybrids containing **cry 1Ac and cry2Ab gene (MON 15985)** at R&D Centre, Haveri District, Karnataka by M/s. Namdhari Seeds Pvt. Ltd., Bangalore.
- 10.5 Permission to conduct **Confined Limited Research Trial (Strip trial)** on **90 Bt cotton hybrids** (HXH) containing **cry 1Ac gene (MON 531 event)** at two locations i.e. Warangal and Yavatmal in **South zone** during Kharif 2007 by M/s. Vibha Agrotech Ltd., Hyderabad.
- 10.6 Permission to conduct **Confined Limited Research Trial (Strip trial)** on **90 Bt cotton hybrids** (HXH) containing *cry 1Ac* and *cry2Ab* genes (MON 15985 event) at two locations i.e. Warangal and Yavatmal in **South zone** during Kharif 2007 by M/s. Vibha Agrotech Ltd., Hyderabad.
- 10.7 Permission to conduct **experimental seed production** of 4 Bt cotton hybrids (H x H) BG-II namely VBCH-1511, VBCH-1512, VBCH-1513 and VBCH-1514 containing *cry1Ac* & *cry2Ab* genes (MON 15985 event) at their own R&D Centre in **Central and South zones** during Kharif 2007 by M/s. Vibha Agrotech Ltd., Hyderabad. The above hybrids have already been approved by RCGM for conducting MLRT during Kharif-2007. The seeds so produced will be utilized for ICAR/ LST trials during Kharif-2008.

1.0 The Committee considered the proposals at agenda 10.1 to 10.7 recommended by RCGM in its meeting held on 24.7.2007. The Committee approved the proposals subject to the standard conditions stipulated by GEAC in agenda items 5.1 to 5.10 above.
