Decisions taken in the 64th Meeting of the Genetic Engineering Approval Committee (GEAC) held on 8th March 2006.

The 64th Meeting of the Genetic Engineering Approval Committee was held on 8th March February 2006 in the Ministry of Environment and Forests under the Chairmanship of Shri B S Parsheera Additional Secretary, MoEF and Chairman GEAC.

Decisions

1.0: Permission for import to conduct phase III clinical trials of r-DNA Liraglutide from M/s Novo Nordisk A/S Denmark by M/s Novo Nordisk India Pvt Ltd, Banglore.

1.1 The Committee noted that the present application received on 17.1.2006 is for import of r-DNA Liraglutide in finished formulations for conduct of phase III clinical trials in India. The Company proposes to conduct a placebo- controlled, double blind-and double- dummy, multicentric, multinational trials in India. The total number of patients would be 160 in 15 centers.

1.2 During the deliberations, some of the Members informed that the project documents were received only on 6.3.2006 and therefore the proposal could not be examined due to paucity of time. Accordingly it was decided to reconsider the proposal in the next GEAC meeting.

1.3 Decision on the proposal was therefore deferred.

2.0: **Permission for manufacture and marketing of tetravalent vaccine DTPw-rHep B by M/s Biological E. Limited, Hyderabad.**

2.1 The Committee noted that the Company has completed the phase –III clinical trials in accordance with the approval of DCGI, GEAC and Human Ethics Committee and the present request is for manufacture and marketing of the product in India. It was noted that the results of the clinical trials concludes that the tetravalent vaccine was found to be safe. No serious adverse events have been reported during the whole study.

2.2 The Committee also considered the comments received from the expert members and noted that the product tetravalent vaccine DTPw-rHep B is a drug approved for marketing in India.

2.3 After detailed deliberations and taking into consideration the recommendation of DBT and Expert Members, the Committee approved the manufacture and marketing of tetravalent vaccine DTPw-rHep B by the Company subject to RCGM recommendation regarding the containment facility and DCGI clearance. It was decided that the GEAC approval will be issued only after review of the RCGM recommendation on the containment facility.

3.0: Permission to import and marketing of Thyrogen from USA by M/s. Sandor Medicaids Pvt. Ltd., Hyderabad.

3.1 The Committee noted that the present application received on 16.2.2006 is for import and marketing of Thyrogen from USA. It was further noted that Thyrogen is a new drug and Phase –III clinical trials in India has not been conducted.

3.2 Member Secretary GEAC informed that as per the prevailing policy, Phase-III clinical trials in India is mandatory. However, in certain cases where the product has been approved for marketing in several countries and the safety and efficacy has been well established or in cases of emergency, DCGI has approved the import without the phase-III clinical trials. Therefore in the instant case, a view of DCGI on this matter needs to be obtained.

3.3 During the deliberations, some of the Members informed that the project documents were received only on 6.3.2006 and therefore the proposal could not be examined due to paucity of time. Accordingly it was decided to reconsider the proposal in the next GEAC meeting after obtaining the views of the Experts and DCGI.

3.4 Decision on the proposal was therefore deferred.

4.0: Permission to conduct phase III Clinical trials of r-DNA combination vaccine (tetravalent vaccine DTPw –r Hep B) by M/s Bharat Biotech International Ltd. Hyderabad.

4.1 The Committee noted that the present application received on 12.2.2006 is for conduct of phase III clinical trials with r-DNA combination vaccine (tetravalent vaccine DTPw –r Hep B) indigenously developed by the Company. The Company proposes to conduct a multi-centric comparative, open labeled Phase III, study to evaluate the efficacy and safety in 110 infants.

4.2 The Committee also noted that the pre-clinical toxicity data generated in laboratory animal system was examined by the RCGM in its meeting held on 2.3.2006 wherein it was concluded that the product was found to be safe for conduct of clinical trials. The Committee further noted that the product tetravalent vaccine tetravalent vaccine DTPw –r Hep B is a drug approved for marketing in India.

4.3 After detailed deliberations and taking into consideration the recommendation of RCGM and the Expert members, the Committee approved the conduct of clinical trials with tetravalent vaccine DTPw –r Hep B subject to DCGI clearance.

5.0: Permission to conduct of phase III Clinical trials of r-DNA combination vaccine (pentavalent vaccine DTPw –r Hep B+ Hib) by M/s. Bharat Biotech Hyderabad.

5.1 The Committee noted that the present application received on 12.2.2006 is for conduct of phase III clinical trials with r-DNA combination vaccine (pentavalent vaccine DTPw –r Hep B+ Hib) indigenously developed by the Company. The Company proposes to conduct a multi-centric comparative, open labeled Phase III, study to evaluate the efficacy and safety in 110 infants.

5.2 The Committee also noted that the pre-clinical toxicity data generated in laboratory animal system was examined by the RCGM in its meeting held on 2.3.2006 wherein it was concluded that the product was found to be safe for conduct of clinical trials. The Committee further noted that the product Pentavalent vaccine DTPw –r Hep B+ Hib is a drug approved for marketing in India.

5.3 After detailed deliberations and taking into consideration the recommendation of RCGM and the Expert members, the Committee approved the conduct of clinical trials with Pentavalent vaccine DTPw –r Hep B+ Hib subject to DCGI clearance.

6.0: Permission for import to conduct phase III Clinical trials of Alfimeprase from USA by M/s Quintiles Research (India) Ltd.

6.1 The Committee noted that the present application received on 15.2.2006 is for import of Alfimeprase from USA for conduct of phase III Clinical trials. The Company proposes to conduct a Multicentric, Multi-National, Randomized, Double- Blind, Placebo- Controlled study to evaluate the efficacy and safety of the drug in 90 subjects at 10 centers in India.

6.2 During the deliberations, one of the members pointed out that the present trial is part of a global clinical trial in which M/s Quintiles is only a CRO. Therefore clarification on whether the drug will be marketed in India needs to be obtained from the manufacturer or the sponsor. The Committee also noted that some of the Expert members have received the project documents only on 7.3.2006 and therefore the proposal could not be examined due to paucity of time. Accordingly it was decided to reconsider the proposal in the next GEAC meeting and also obtain clarification on whether the manufacturer/sponsor proposes to market the drug in India

6.3 Decision on the proposal was therefore deferred.

B. Pharmaceuticals (Reconsideration case).

7.0: Revalidation permission for import and marketing of r-human insulin by M/s Sun Pharmaceuticals Ltd. Mumbai.

7.1 The Committee noted that the above request for revalidation of the GEAC permission for import and marketing of r-human insulin by Sun Pharmaceuticals Ltd was considered by the GEAC in its meeting held on 13.1.2006 wherein the company was advised to confirm the source from where r-human insulin is being procured, the type of formulations produced and the quantity of the drug marketed by the Company in India at present and during the last 3 years.

7.2 The Committee noted that r-human insulin is being procured from M/s Eli Lilly Export S.A, Switzerland for which the approval of GEAC has been obtained. The Committee also took note of the information regarding the type and quantity of formulations manufactured by the Company.

7.4 After detailed deliberations, the Committee conveyed their no objection for revalidating the GEAC permission dated 29.7.1994 for import and marketing of r-human insulin by M/s Sun Pharmaceuticals Ltd. Mumbai.

C. Transgenic Crops
(Commercial release in North Zone)

a. The Member Secretary briefed the Committee on the regulatory requirement/ policy decisions taken by GEAC. The following points were noted:

1 Prior to the commercial release of Bt cotton hybrids, report of the MEC on the large scale trials (LST), recommendations of RCGM and ICAR and completion of biosafety assessment studies is mandatory.

2 Regarding number of years for LST, as per the decision taken in the GEAC meeting held on 4.3.2005, the Company is required to undergo two years of LST. However, it may be noted that in the same year, GEAC had approved commercial release of six Bt cotton hybrids for the North Zone based on one year LST. To resolve the discrepancy, it was decided to refer the matter to sub-committee under the Dr. S. Nagrajan.

3. The report of the sub –committee was considered by the GEAC in its meeting held on 8.2.2006, wherein it was concluded that the matter may be referred back to the sub-Committee for its reconsideration in the light of the views expressed by the members of the GEAC and also representations given from time to time by the industry representatives. The Committee further recommended that two more members (Dr R P Sharma and Dr Sushil Kumar) may be co-opted in the Sub-Committee in view of their expertise on the subject matter. It was also decided that the new policy and procedures would be applicable in prospective for new cases only and not retrospectively. It was also agreed that the new cases would mean those hybrids which have not been approved by the GEAC for large scale trials. The matter was referred back to the Chairman of the sub-Committee but Dr Nagarajan, in view of his new assignment as Chairman of the PVPFR Authority has conveyed his inability to accept the Chairmanship of the sub-Committee

4. As per the present requirement of Seed Policy, two years of ICAR trial is mandatory except for centrally notified varieties.

5. Regarding seed production it was decided in the GEAC meeting held on 20th May 2005 that seed production may be permitted in an area up to 20 acres wherever permission has been given for one year trials. It was also decided that the above decision will be applicable for commercially released events only. All new genes/events will undergo two years of large-scale trials. In such cases seed production in an area of 1 acre is adequate. The Sub Committee under Dr Nagarajan has recommended that " For situations where two years of LST/ICAR are essential then for the first year seed production of 10 hectares and during second year LST/ICAR trial 100 hectares can be given".

6. In the 41st meeting of the GEAC it was decided that large scale trials will be conducted at 80 locations / zone / genotype. This has been rationalized in the sub-Committee report taking into consideration the area under cotton cultivation and agro-climatic zones.

7. Prior to approval of LST, recommendation of RCGM and MEC on the results of the contained trials is mandatory.

8. The GEAC has approved 6 Bt cotton hybrids containing cry 1 Ac gene Mon 531 event for commercial cultivation in the North and a total of 20 hybrids containing the same gene event in the three zones.

b. Before considering the individual proposals, the Committee deliberated at length on each of the policy issues mentioned above. Views were expressed by some Members that there is a urgent need to firm up a uniform policy in respect of Protocols for LST seed production, parameters to be considered for commercial release etc to avoid any inconsistency in the GEAC decision. The Chairman invited Dr B M Khadi, Director CICR and representative of ICAR to present the findings of AICCIP trials. Dr Khadi informed that 12 Bt hybrids have been evaluated by ICAR for a period of two years, at five locations of which RCH 314 was the most promising with mean seed cotton yield of 3356 Kg/ha followed by RCH 308 Bt and MRC 6029. He pointed out that the yield of three hybrids was about 36%, 25% and 20% more than the mean Bt checks whereas other hybrids was lower or almost equal to the mean Bt checks. Of the hybrids containing the new gene it was noted that JKCH 2226 Bt showed an increase of 17 % over the mean Bt check whereas JKCH 1050 Bt showed a increase of only 3%. The mean seed cotton yield of NECH 3R and NECH 6 R was noted to be significantly lower (- 42% and – 9 % respectively) than the mean BT check. The Committee also noted that during the first year of ICAR trial, the Bt hybrids were evaluated against non Bt checks and during the second year ICAR trials, the Bt hybrids were evaluated against Bt checks. During the deliberations it was also pointed out that the hybrids not recommended by ICAR have performed better or equal to the hybrids approved for commercial release by GEAC. Dr Khadi clarified that the intention was to provide the best available material to the farmers as increase in yield by one quintal can fetch an additional price of Rs 2000. Dr Khadi further, informed the Committee that under the ICAR system, even for non Bt cotton hybrids, only hybrids having a yield more than 20% of the best local checks are approved by the ICAR. In response to the statement made by Dr Khadi, views

were expressed that in case of Bt cotton, the need for introducing market competitiveness to make the Bt seeds affordable to small farmers also needs to be addressed. Views were also expressed that yield cannot be the only criteria for deciding the promising hybrid. It was suggested that parameters such as level of protein expression, staple length, boll size, susceptibility to diseases, etc should also be taken into consideration while selecting promising hybrids. In light of the above discussion, the GEAC requested ICAR to give their considered opinion on the performance of each of 12 hybrid and its susceptibility to CLCUv expeditiously.

c. The Committee further considered the recommendations of MEC and RCGM and noted that the MEC based on the evaluation of large scale trials at 80 locations has recommended MRC 6025 Bt, MRC 6029 Bt, NCS 913 Bt, NCS 138 Bt, NECH 6 R, RCH 308 Bt, RCH 314 Bt and JKCH 1947 Bt for commercial release. The Committee noted that the recommendation of ICAR and MEC/RCGM are at variance. It was pointed out that results of ICAR trials are based on field trials at 5 locations and that of MEC is at 80 locations. Also the protocols for ICAR trials and LST under GEAC are different.

d. The Committee also discussed the recommendation of MEC in respect of Bt cotton hybrids approved for LST. It was noted that RCGM has recommended 37 hybrids for LST. The representation of ICAR informed that ICAR is not in a position to accept more than 25 hybrids / zone and accordingly each Company may request to present their best entry. Views were expressed that restricting the number, in terms of per Company, some of the best entries of would be left out and the options available to farmers would be limited.

e. In view of the above deliberations and taking into consideration that Dr S Nagarajan has conveyed his regret in being the Chairman of the sub-Committee and also taking into account the GEAC decision to include two more experts, namely Dr R P Sharma and Dr Sushil Kumar in the Sub-Committee, it was decided that the sub-Committee earlier chaired by Dr Nagarajan would be Chaired by Dr R P Sharma and Dr Sushil Kumar be included as Member of the sub-committee. The TOR of the sub-Committee would be as follows:

i. To recommend the period of Large Scale Trials and seed production for transgenic cotton for CVRC notified and un-notified varieties in both released gene /event & new gene/event.
ii. To recommend the period of Large Scale Trials and seed production for new gene in new crops.
iii. Review of GEAC compliance conditions in respect of refugia, IRM practice, IPM strategy, appropriate packaging practice etc.
iv. Parameters and benchmark for deciding the superiority of the hybrids evaluated under MEC / ICAR system.
v. Any other recommendation on related aspects.

f. Subsequent to the above discussions and decisions the GEAC briefly considered the following proposals.

8.0: Permission for commercial release of Bt Cotton hybrid MRC-6025 Bt and MRC-6029 Bt for North Zone containing cry 1Ac gene by M/s Mahyco, Mumbai.

8.1 The Committee noted that the present application received on 20.2.2006 is for commercial release and marketing of MRC-6025 Bt and MRC-6029 Bt containing Cry 1 A(c) gene Mon 531 event, in the North zone. In accordance with the GEAC decision dated 4.3.2005 the Company has completed the first year 'Large Scale Field (LST)' during Kharif 2005. The field trials have been monitored by MEC. The MEC and RCGM have recommended the suitability of both MRC 6025 Bt and MRC 6029 Bt for commercial cultivation in the North zone.

8.2 The hybrids have completed two year of ICAR trials. As per the ICAR report, the overall performance of MRC 6029 Bt ranks third. It was noted that ICAR has not given its

considered opinion on the susceptibility of this hybrid to CLCUv. The representative of ICAR was requested to forward the same to the GEAC

8.3 In view of the GEAC decision to set up a sub-committee and clarifications awaited from ICAR, decision on the proposal was deferred.

9.0: Permission for commercial release of Bt Cotton hybrid NCS-913 BT and NCS-138 for North Zone by M/s Nuziveedu Seeds Ltd. Secundrabad

9.1 The Committee noted that the present application received on 13.2.2006 is for commercial release and marketing of NCS-913 Bt and NCS-138 containing Cry 1 A(c) gene Mon 531 event, in the North zone. In accordance with the GEAC decision dated 4.3.2005 the Company has completed the first year LST during Kharif 2005. The field trials have been monitored by MEC. The MEC and RCGM have recommended the suitability of both NCS-913 Bt and NCS-138 Bt for commercial cultivation in the North zone.

9.2 The hybrids have also completed two years of ICAR trials under the AICCIP. ICAR has not recommended both the hybrids for North zone on the ground that the mean seed yield is less than the Bt check.

9.3 In view of the GEAC decision to set up a sub-committee and clarifications awaited from ICAR, decision on the proposal was deferred.

10.0: Permission for commercial release of Bt Cotton Hybrid NCEH-6 Bt containing (cry 1Ab+ 1 Cry Ac) for North Zone by M/s Nath Seeds.

10.1 The Committee noted that the present application received on 21.2.2006 is for commercial release and marketing of NCEH-6 Bt containing encoding fusion gene (cry 1Ab+ 1 Cry Ac) in the North zone. In accordance with the GEAC decision dated 13.4.2005 the Company has completed the first year LST during Kharif 2005. The field trials have been monitored by MEC. The MEC and RCGM have recommended the suitability of NCEH-6 Bt for commercial cultivation in the North zone.

10.2 The hybrid has also completed two years of ICAR trials under the AICCIP. ICAR has not recommended the hybrids for North zone on the ground that the mean seed yield is less than the Bt check.

10.3 The Committee noted that the Company has completed the biosafety studies authorized by RCGM. The data from the biosafety studies have been have been presented before the RCGM in its meeting held on 2.3.2006. Member Secretary RCGM was requested to forward the recommendations of RCGM to the GEAC. During the deliberations, one of the Members pointed out that the biosafety studies have been completed before the hybrid was permitted for LST. It was clarified that the biosafety component in terms of environmental safety was completed in Kharif 2005. However the food and feed safety has only recently been completed.

10.4 In view of the GEAC decision to set up a sub-committee and clarifications awaited from ICAR, decision on the proposal was deferred. As NCEH-6 Bt contains a new genes (cry 1Ab+ 1 Cry Ac), it was further decided to invite the Company representative to make a detailed presentation on the biosafety data during the next GEAC meeting.

11.1: Permission for commercial release of Bt Cotton hybrid RCH-308 Bt and RCH-314 Bt containing (cry 1Ac gene) for North Zone by M/s Rasi Seeds Ltd.

11.1 The Committee noted that the present application received on 22.2.2006 is for commercial release and marketing of RCH-308 Bt and RCH-314 Bt containing Cry 1 A(c) gene Mon 531 event, in the North zone. In accordance with the GEAC decision dated 4.3.2005 the Company has completed the first year LST during Kharif 2005. The field trials have been monitored by MEC. The MEC and RCGM have recommended the suitability of both RCH-308 Bt and RCH-314 Bt for commercial cultivation in the North zone

11.2 The hybrids have also completed two years of ICAR trials under the AICCIP. The reports of the ICAR have been received. As per the ICAR report, the overall performance of RCH 314 and RCH 308 Bt ranks first and second. It was noted that ICAR has not given its considered opinion on the susceptibility of this hybrid to CLCUv. The representative of ICAR was requested to forward the same to the GEAC

11.3 In view of the GEAC decision to set up a sub-committee and clarifications awaited from ICAR, decision on the proposal was deferred.

12.0 Permission for commercial release of Bt Cotton hybrid JKCH-1947 Bt containing (cry 1Ac gene) for North Zone by M/s J. K. Agri Genetics Ltd.

12.1 The Committee noted that the present application received on 22.2.2006 is for commercial release and marketing of JKCH-1947 Bt containing (cry 1Ac gene) developed indigenously through IIT Kharagpur, in the North zone. In accordance with the GEAC decision dated 13.4.2005 the Company has completed the first year LST during Kharif 2005. The field trials have been monitored by MEC. The MEC and RCGM have recommended the suitability of JKCH-1947 Bt for commercial cultivation in the North zone.

12.2 The hybrid has also completed two years of ICAR trials under the AICCIP. ICAR has not recommended the hybrids for North zone on the ground that the mean seed yield is less than the Bt check.

12.3 The Committee noted that the Company has completed the biosafety studies authorized by RCGM. The data from the biosafety studies have been have been presented before the RCGM in its meeting held on 2.3.2006. Member Secretary RCGM was requested to forward the recommendations of RCGM to the GEAC. During the deliberations, one of the Members pointed out that the biosafety studies have been completed before the hybrid was permitted for LST. It was clarified that the biosafety component in terms of environmental safety was completed in Kharif 2005. However the food and feed safety has only recently been completed.

12.4 In view of the GEAC decision to set up a sub-committee and clarifications awaited from ICAR, decision on the proposal was deferred. As JKCH-1947 Bt containing (cry 1Ac gene) it was further decided to invite the Company representative to make a detailed presentation on the biosafety data during the next GEAC meeting.

D. Large Scale Trials in the North Zone (Subsequent to RCGM trials and MEC evaluation)

13.0 Permission for Large scale trials of Bollgard II Cotton hybrid MRC-7017 BG II and MRC-7031 BG II for North Zone by M/s Mahyco, Mumbai.

13.1 The Committee noted that the present application received on 27.3.2006 is for conducting large scale field trials of MRC-7017 BG II, MRC-7031 BG II containing Cry X (Cry I A c and Cry 2 Ab) genes (event MON 15985) at 40 locations in the North Zone for the second year LST.

13.2 The Committee noted that the GEAC in its meeting held on 4.3.2006 had approved large scale trials of MRC-7017 BG II, MRC-7031 BG II at 80 locations in North Zone during Kharif 2005 based on the recommendations of RCGM and MEC. The first year LST as recommended by GEAC have been completed. The field trials have been monitored by MEC. The MEC and RCGM have recommended both the hybrids for commercial release. However, the Company has requested permission to repeat the LST during Kharif 2006. The present request is for conducting second year LST.

13.3 The Company has also completed the biosafety studies authorized by RCGM. The biosafety studies have been have been presented before the RCGM in its meeting held on 27.10.2005. Recommendations of the RCGM on the efficacy and safety of the new genes has been received. It was also decided in the above meeting that the entire biosafety studies be forwarded to Dr B M Khadi for his comments. The recommendations of RCGM and Dr B M Khadi, Director CICR indicate that Bt cotton hybrids expressing Cry 1 Ac & Cry 2 Ab (event No 15985) are as safe non-transgenic cotton without any appreciable environmental risks.

13.4 In view of the above stated facts, the GEAC approved the conduct of second year LST with MRC-7017 BG II, MRC-7031 BG I in the North zone during Kharif 2006.

14.0 Permission for seed production and large scale trials of transgenic cotton hybrids GK 206 Bt and GK 210 Bt for North Zone by M/s Ganga Kaveri Seeds Pvt Ltd. Hyderabad.

14.1 The Committee noted that the application received on 10.2.2006 is for conducting large scale field trials of GK 206 Bt and GK 210 Bt containing Cry 1 Ac gene Mon 531 event in the north zone at 40/80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended both the hybrids for LST.

14.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

14.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

15.0: Permission for seed production and large scale trials of transgenic cotton hybrids ACH-33-1, ACH-155-1, ACH-Gaurav-1 by M/s Ajeet Seeds Ltd. Aurangabad.

15.1 The Committee noted that the application received on 14.2.2006 is for conducting large scale field trials of ACH-33-1, ACH-155-1, ACH-Gaurav-1 containing Cry 1 Ac gene Mon 531 event in the north zone at 40 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended ACH-33-1 and ACH-155-1 for LST.

15.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

15.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

16.0: Permission for seed production and large scale trials of transgenic cotton hybrids ACH-155-2 (Ajeet 155), ACH-33-2 (Ajeet- 33) & ACH-21-2 (Ajeet-21) by M/s Ajeet Seeds Ltd. Aurangabad.

16.1 The Committee noted that the application received on 14.2.2006 is for conducting large scale field trials of ACH-155-2 (Ajeet 155), ACH-33-2 (Ajeet- 33) & ACH-21-2 (Ajeet-21 containing Cry 1 Ac gene Mon 531 event in the north zone at 40/80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended ACH-155-2 (BG II) and ACH-33-2 (BG II) for LST.

16.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

16.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

17.0: Permission for seed production and large scale trials of transgenic cotton hybrids NCS-145 (Bunny) Containing Cry 1Ac+Cry 2 Ab by M/s Nuziveedu Seeds Ltd. Secundrabad.

17.1 The Committee noted that the application received on 14.2.2006 is for conducting large scale field trials of NCS-145 (Bunny) Containing Cry 1Ac+Cry 2 Ab containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended the hybrid for LST.

17.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

17.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

18.0: Permission for large scale trials of Bt Cotton hybrid RCH-134 Bt BG II and RCH-539 BG II and RCH-542 BG II containing (cry 1Ac + cry 2Ab) gene for North Zone by M/s Rasi Seeds Ltd

18.1 The Committee noted that the application received on 22.2.2006 is for conducting large scale field trials of RCH-134 Bt BG II and RCH-539 BG II and RCH-542 BG II containing (cry 1Ac + cry 2Ab) gene containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during Kharif 2005. The field trials have been monitored by MEC. MEC has recommended all the three hybrids for LST.

18.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

18.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

19.0: Permission for seed production and large scale trials of transgenic cotton hybrids 6317-2 Bt and 6488-2 Bt (Mon-15985) by M/s BioSeeds Research India Pvt. Ltd. Hyderabad.

19.1 The Committee noted that the application received on 28.2.2006 is for conducting large scale field trials of 6317-2 Bt and 6488-2 Bt (Mon-15985) containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended both the hybrids for LST.

19.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

19.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

20.0: Permission for seed production and large scale trials of transgenic cotton hybrids 6317 Bt and 563 Bt (Mon-531) by M/s BioSeeds Reserch India Pvt. Ltd. Hyderabad.

20.1 The Committee noted that the application received on 28.2.2006 is for conducting large scale field trials of 6317 Bt and 563 Bt (Mon-531) containing Cry 1 Ac gene Mon 531 event in the north zone at 40 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended both the hybrids for LST.

20.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

20.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

21.0: Permission for seed production and large scale trials of transgenic cotton hybrids NAMCOT 401 Bt and NAMCOT 402 (Mon-531) by M/s Namdhari Seeds Pvt. Ltd. Banglore

21.1 The Committee noted that the application received on 28.2.2006 is for conducting large scale field trials of NAMCOT 401 Bt and NAMCOT 402 (Mon-531) containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended only NAMCOT – 402 for LST.

21.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

21.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

22.0: **Permission for seed production and large scale trials of transgenic cotton hybrids MLCH 315 BG II and Krishna BGII by M/s Emergent Genetics India Pvt. Ltd.**

22.1 The Committee noted that the application received on 2.3.2006 is for conducting large scale field trials of MLCH 315 BG II and Krishna BGII containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended only MLCH-315 BG II for LST.

22.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

22.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

23.0: Permission for seed production and large scale trials of transgenic cotton hybrids IT-903 and IT 905 by M/s Proagro Seeds Company Pvt. Ltd.

23.1 The Committee noted that the application received on 24.2.2006 is for conducting large scale field trials of hybrids IT-903 and IT 905 containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended only IT – 903 for LST.

23.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

23.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

24.0: Permission for large scale trials of transgenic cotton hybrids Tulasi 9, Tulasi 5, Tulasi 18 by M/s Tulasi Seeds Pvt. Ltd.

24.1 The Committee noted that the application received on 22.2.2006 is for conducting large scale field trials of Tulasi 9, Tulasi 5, Tulasi 18 containing Cry 1 Ac gene Mon 531 event in the north zone. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has not recommended any of the above hybrids for LST.

24.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

24.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

25.0: Permission for large scale trials of transgenic cotton hybrids Tulasi 4 BG II, Tulasi 9 BG II, Tulasi 117 BG II by M/s Tulasi Seeds Pvt. Ltd.

25.1 The Committee noted that the application received on 28.2.2006 is for conducting large scale field trials of Tulasi 4 BG II, Tulasi 9 BG II, Tulasi 117 BG II containing Cry 1 Ac gene Mon 531 event in the north zone. In accordance with the RCGM approval, the Company has conducted multi-locational trials during kharif 2005. The field trials have been monitored by MEC. MEC has recommended Tulasi – 4 BG II and Tulasi – 9 BG II for LST.

25.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

25.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

26.0: Permission for seed production and large scale trials of transgenic cotton hybrids Sigma Bt and Ole Bt by M/s Vibha Agrotech Ltd. Hyderabad.

26.1 The Committee noted that the application received on 28.2.2006 is for conducting large scale field trials of Sigma Bt and Ole Bt containing Cry 1 Ac gene Mon 531 event in the north zone at 80 locations. In accordance with the RCGM approval, the Company has conducted multi-locational trials during Kharif 2005. The field trials have been monitored by MEC. MEC has recommended both the hybrids for LST.

26.2 The Company has also requested for seed production of the above cotton hybrids in an area of 100 acres for each hybrid.

26.3 In view of the GEAC decision to set up a sub-committee, decision on the proposal was deferred.

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