

**Decisions taken in the 53<sup>rd</sup> Meeting of the Genetic Engineering Approval Committee (GEAC) held on 13<sup>th</sup> April 2005.**

The 53<sup>rd</sup> Meeting of the Genetic Engineering Approval Committee was held on 13<sup>th</sup> April 2005 in the Ministry of Environment and Forests under the Chairmanship of Shri Suresh Chandra, Special Secretary & Chairman GEAC.

Before taking up the items on the Agenda for the meeting, the Committee considered the request from Gene Campaign, Greenpeace, Federation of Farmers Association, Karnataka and Confederation of Indian Farmers Association and gave an opportunity to present their views and experience with Bt Cotton.

**4.1 Permission for commercial release of Bt cotton hybrids NCS-145, 'Bunny' Bt, NCS –207 'Mallika' Bt for Central Zone by M/s Nuziveedu Seeds Ltd.**

- a) In the absence of ICAR report, decision on whether to permit NCS-145, 'Bunny' Bt, NCS –207 'Mallika' Bt for commercial release was deferred.

**4.2 Permission for commercial release of RCH – 138 Bt and RCH –144 Bt, RCH – 118 Bt and RCH –359 Bt for Central zone by M/s Rasi Seeds.**

- a) In the case of RCH 138 Bt hybrid taking into consideration the results of the two years large scale trials and two years ICAR trials as well as recommendations of MEC and ICAR, the Committee approved the commercial release of **RCH 138 Bt** for the Central Zone.
- b) In the case of **RCH 144 Bt**, it was decided to await the clarification from MEC regarding its recommendation for commercial release for a period of two years only while approval is generally for three years.
- c) In the absence of ICAR recommendation decision on whether to permit commercial release of **RCH 118 Bt** hybrid was deferred.
- d) Since MEC has not recommended **RCH 359 Bt** was rejected by the Committee for commercial release.

**4.3 Permission for commercial release of BG-I Hybrids MRC – 6160 Bt, MRC-6301 Bt and MRC-6304 Bt for Central Zone by M/s Mahyco.**

- a) In the absence of ICAR recommendation decision on whether to permit commercial release of **MRC-6301 Bt and MRC-6304 Bt** hybrid was deferred.
- b) Since MEC has not recommended – **6160 Bt**, RCH 359 Bt was rejected by the Committee for commercial release.

**4.4 Permission for commercial release of Ankur-651 and Ankur-09 for Central Zone by M/s Ankur Seeds Pvt. Ltd.**

- a) In the absence of ICAR recommendation decision on whether to permit commercial release of **Ankur-651 and Ankur-09** hybrid was deferred.

**4.5 Renewal of GEAC permission for commercialization of three Bt. Cotton hybrids namely MECH – 12 Bt, MECH – 162 Bt, and MECH – 184 Bt containing with Cry 1 Ac gene developed by M/s Mahyco in Central and South zones.**

1. The Committee decided to obtain the explicit views of the State Govt on the following issues:
  - a) Whether the Bt technology introduced in cotton crop has been beneficial to the farmers in the respective States.
  - b) Whether the overall productivity of cotton crop in general has increased over the period 2002 to 2005 in the respective States.
  - c) Any other findings specific to an area were observed.
2. It was agreed that a time frame of ten days may be given to the State Govt for clarifying the above issue and the proposal may be placed before the GEAC in the next meeting for taking a final view.

**B. Transgenic Crops (Large Scale Trials in Central Zone subsequent to RCGM trials and MEC evaluation)**

**Central Zone**

**4.6 Permission for large Scale trials and seed production of VCH-110 Bt, VCH-111Bt, VCH-112 Bt by M/s Vikki Agrotech Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit VCH-111 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended VCH-110 Bt & VCH-112 Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.7 Permission for large Scale trials and seed production of GK-204Bt, GK-205Bt and GK-206 Bt by M/s Ganga Kaveri Seeds.**

- a) In the absence of the RCGM recommendation, decision on whether to permit GK-204 Bt & GK-205 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended GK-206 Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.8 Permission for large Scale trials and seed production of PRCH-101 Bt, PRCH-102 Bt and PRCH-103 Bt by M/s. Paravardhan Seeds Pvt. Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit PRCH-102 Bt, for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended PRCH-101 Bt & PRCH-103 Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.9 Permission for large scale trials and seed production of Bt. Cotton hybrids NPH-2270, NPH-2171 and NPH-2250 by M/s Prabhat Agri Biotech Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit NPH-2171 for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended NPH-2270 & NPH-2250 for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.10 Permission for large scale trials & Seed Production for RCH 377 Bt, RCH-380 Bt and RCH –386 Bt by M/s Rasi seeds.**

- a) In the absence of the RCGM recommendation, decision on whether to permit RCH 377 Bt & RCH –386 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended RCH-380 Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.11 Permission for large-scale trials of ACH-155-1 and ACH 21-1 with Cry 1 Ac gene in the North Zone by M/s Ajeet Seeds.**

- a) In the absence of the RCGM recommendation, decision on whether to permit ACH-155-1 for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended ACH 21-1 for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.12 Permission for large scale trials & seed Production of Tulsi 4 Bt, Tulsi –117 Bt, Tulsi-5 Bt, Tulsi –9 Bt and Tulsi-18 Bt by M/s Tulsi Seeds Pvt. Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit Tulsi 4 Bt & Tulsi –117 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended Tulsi-5 Bt, Tulsi –9 Bt, Tulsi-18 Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.13 Permission for large scale trials & seed production in Brahma Bt, Krishna Bt, Kirtiman and Dhanwan Bt, Chetana Bt, Ram-2 Bt, Paras Laxmi and Rukmini Bt by M/s Emergent Genetics India Pvt. Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit Brahma Bt in the Central Zone was deferred.
- b) Since MEC has not recommended Krishna Bt, Kirtiman and Dhanwan Bt, Chetana Bt, Ram-2 Bt, Paras Laxmi & Rukmini Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.14 Permission for large scale trials of NCS-138 Bt, NCS 570 Bt and NCS 913 Bt and seed production by M/s. Nuziveedu Seed Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit NCS 913 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended NCS-138 Bt & NCS 570 Bt for large-scale trials in the Central Zone, the Committee rejected the request for the same.

**4.15 Permission for large scale trials & seed production of Brahma BG-II Bt, Krishna BG-II Bt, Kirtiman BG-II and Paras Laxmi BG-II by M/s Emergent Genetics India Pvt. Ltd.**

- a) The Committee noted that no data has been presented for consideration of the MEC. Since evaluation and recommendation MEC is pre-requisite for consideration of the proposal for large scale trials, the Committee rejected the request for the same.

**4.16 Permission for large scale trials & seed production of KDCHH-9632 Bt, KDCHH-09 Bt, KDCHH -351 Bt, KDCHH- 9821 Bt, KDCHH -9810 Bt, BG-I by M/s Krishidhan Seeds Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit KDCHH -9810 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended KDCHH-9632 Bt, KDCHH-09 Bt, KDCHH -351 Bt, KDCHH- 9821 Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.17 Permission for large scale trials and seed production of KDCHH-621 BG-II, KDCHH-441 BG-II and KDCHH-531 BG- by M/s Krishidhan seeds Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit KDCHH-621 BG-II & KDCHH-441 BG-II for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended KDCHH-531 BG- II for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.18 Permission for large scale trials & seed production of cotton hybrids RCH-512 BGII, RCH 515 BGII and RCH 521 BGII by M/s Rasi Seeds.**

- a) In the absence of the RCGM recommendation, decision on whether to permit RCH 515 for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended RCH-512 BG II & RCH 521 BG II for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.19 Permission for large scale trials of BGII, Cotton hybrids MRC-7160 BGII , MRC-7201 BGII, MRC- 7301 BGII, and MRC-7326 BGII for the second year and first year large scale trials of MRC-7351 BGII, MRC-7341 BGII, MRC-7347 BGII and seed production by M/s Mahyco.**

- a) In the absence of the RCGM recommendation, decision on whether to permit MRC- 7301 BG II, MRC-7326 BG II, MRC-7351 BG II, MRC-7341 BG II, MRC-7347 BG II for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended MRC-7160 BG II & MRC-7201 BG II for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.20 Permission for large scale trials and seed production of JK-Durga Bt, JK-Varun, JKCH 666 Bt, JKCH 99 Bt, JKCH 226 Bt and JKCH 634 (Ishwar) Bt by M/s J.K. seeds.**

- a) In the absence of the RCGM recommendation, decision on whether to permit JK-Varun, JKCH 99 Bt for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended JK-Durga Bt, JKCH 666 Bt, JKCH 226 Bt, JKCH 634 (Ishwar) Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.21 Permission for large scale trials and seed production of hybrids NCEH-2R Bt and NCEH-3R Bt by M/s. Nath Seeds Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit NCEH-2R Bt,for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended NCEH-3R Bt for large scale trials in the Central Zone, the Committee rejected the request for the same.

**4.22 Permission for large scale trials and seed production of hybrids 02- 41 Vip, 02-58 Vip containing 'vip3A' gene by M/s Syngenta Seeds India Ltd.**

- a) In the absence of the RCGM recommendation, decision on whether to permit 02- 41 Vip for conduct of large scale trials in the Central Zone was deferred.
- b) Since MEC has not recommended 02-58 Vip for large scale trials in the Central Zone, the Committee rejected the request for the same.

### North Zone

#### **4.23 Permission for large scale trials & seed production of Chetana Bt, Rukmini Bt, Ram-2 Bt, Brahma Bt, Kirtiman Bt, Dhanwan Bt, and Krishna Bt by M/s. Emergent Genetics India Pvt. Ltd.**

- a) Since MEC has not recommended any of the hybrids for large scale trials in the North Zone, the GEAC rejected the request of the Company.

#### **4.24 Permission for large Scale trials and seed production of JKCH-1050 Bt and JKCH-1947 Bt by M/s J. K. Seeds.**

1. Noting the findings of the contained field trials and recommendation of MEC and RCGM, the GEAC approved large scale trials of **JKCH 1947 Bt** at 80 representative locations per genotype per zone and seed production for each variety with the following conditions:
  - a) The applicant should look for the incidence of sucking pests on these hybrids during large-scale trials and also artificial screening for CLCV resistance.
  - b) The Agricultural Universities would be involved in the monitoring of large scale trials with specific reference to incidence of CLCV.
  - c) These large scale trials may be monitored by the MEC.
2. Since MEC has not recommended JKCH-1050 Bt for large scale trials in the North Zone, the Committee rejected the request for the same.

#### **4.25 Permission for large scale trials and seed production of hybrids NCEH-6 Bt and NCEH-3R Bt by M/s. Nath Seeds Ltd.**

1. Noting the findings of the contained field trials and recommendation of MEC and RCGM, the GEAC approved large scale trials of **NCEH 6 R** at 80 representative locations per genotype per zone and seed production in an area of 100 ha with the following conditions:
  - a) The applicant should look for the incidence of sucking pests on these hybrids during large-scale trials and also artificial screening for CLCV resistance.
  - b) The Agricultural Universities would be involved in the monitoring of large scale trials with specific reference to incidence of CLCV.
  - c) These large scale trials may be monitored by the MEC.
2. Since MEC has not recommended NCEH-3R Bt for large scale trials in the North Zone, the Committee rejected the request for the same.

#### **4.26 Permission for large scale trials of hybrids 02-42 Vip, 02-50 Vip containing 'vip3A' gene by M/s Syngenta Seeds India Ltd.**

1. Noting the findings of the contained field trials and recommendation of MEC and RCGM, the GEAC approved large scale trials of **02-50 Vip Cotton** at 80 representative locations per genotype per zone with the following conditions:
  - a) The applicant should look for the incidence of sucking pests on these hybrids during large-scale trials and also artificial screening for CLCV resistance.

- b) The Agricultural Universities would be involved in the monitoring of large scale trials with specific reference to incidence of CLCV.
  - c) These large scale trials may be monitored by the MEC.
2. Since MEC has not recommended 02-42 Vip for large scale trials in the North Zone, the Committee rejected the request for the same.

### **C. Transgenic Crops (Direct GEAC Large Scale Trials)**

#### **Central Zone**

#### **4.27 Permission for large scale trials and seed production of hybrids NCS-914 Bt, NCS-915 Bt and NCS-918 Bt, NCS-922 Bt, NCS-929 Bt and NCHB-945 Bt by M/s. Nuziveedu seeds Ltd.**

1. It was decided to constitute a sub-Committee with the following members to examine the case verification documents submitted by the applicants and recommend to the GEAC the suitability of the hybrids for large scale trials in the respective zones:
  - a) Shri R P Sharma, Member GEAC
  - b) Dr N T Mahapatra, Director, NBPGR
  - c) Dr P S Dhillon, Scientist, NBPGR
  - d) Dr K K Kranthi, Scientist, CICR.
  - e) Dr T V Ramaniah, Director DBT & Member Secretary RCGM.
2. The Committee nominated Dr TV Ramaniah as the Convener of the sub-Committee. The sub-Committee will submit its recommendation to the GEAC before the next meeting.
3. The Committee also took a view that applicants who have not submitted the relevant case verification documents, the proposals may be treated as pre-mature for consideration for large-scale trials.

#### **4.28 Large scale trial BCHH 302 Bt Bajrang and BCHH 322 Bt containing Cry 1 Ac by M/s Bioseeds Research India Pvt. Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the Central Zone.

#### **4.29 Permission for large scale trials and seed production of Bt cotton hybrids VICH-9, VICH-5, VICH-11 and VICH-15 by M/s. Vikram Seeds Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the Central Zone.

**4.30 Permission for large scale trials & seed production of PCH- 917I Bt. (NCS 917Bt.), PCH-923 Bt.(NCS-923) PCH-927Bt.(NCS 927Bt.) and ) PCH-930Bt.(NCS 930 Bt.) by M/s Prabhat Agri Biotech.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the Central Zone.

**4.31 Permission for large scale trials and seed production of hybrids Nandi 405, Nandi 45 and 36 by M/s Nandi Seeds (P) Ltd.**

1. The Committee noted that the applicant has not submitted the requisite case verification documents and concluded that those applicants who have not submitted the relevant case verification documents, the proposals may be treated as premature for consideration for large-scale trials. The Committee therefore rejected the request.

**4.32 Large scale trial BCHH 322 –2 BG II I & BCHH 557- 2 B-G II containing Cry X gene(s) by M/s Bioseeds.**

1. The Committee noted that the present request is for direct entry into GEAC large-scale trials of those hybrids, which have not been approved by GEAC, and therefore the 'case verification' would not be applicable in such case. The Committee therefore rejected the request and directed the applicant to approach RCGM for conduct of multi-locational trials.

**North Zone**

**4.33 Permission for large scale trials of BCHH - 6317 – Bt and HE- 563 Bt with Cry 1 Ac gene in the North Zone and seed production by Bioseed Research India Pvt. Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.34 Permission for large scale trials and seed production of hybrids NCS-914 Bt, NCS-915 Bt and NCS-918 Bt by M/s. Nuziveedu seeds Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.35 Permission for large scale trials & seed Production of Tulsi 4 Bt, Tulsi –117 Bt, Tulsi-5 Bt, Tulsi –9 Bt and Tulsi-18 Bt by M/s Tulsi Seeds Pvt. Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification



documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.36 Permission for large scale trials and seed production of Bt. Cotton hybrids NPH-2270, NPH-2171 and NPH-2250 by M/s Prabhat Agri Biotech Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.37 Permission for large scale trials and seed production of Bt cotton hybrids VICH-9 and VICH-11 by M/s. Vikram Seeds Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.38 Permission for large scale trials & seed production of Quick 351 Bt (KDCHH -351 Bt), Surya 144 Bt (KDCHH -144 Bt ), KDCHH-702 Bt, KDCHH-603 Bt, KDCHH- 801 Bt, BG-I by M/s Krishidhan Seeds Ltd.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.39 Permission for large scale trials & seed production of PCH- 917 Bt. (NCS 917 Bt.), PCH-923 Bt (NCS-923), PCH-927 Bt (NCS 927Bt) and PCH-930 Bt (NCS 930 Bt) all containing Cry 1Ac gene by M/s Prabhat Agri Biotech.**

1. In accordance with the decision taken, at agenda item 4.27, it was decided to place the request for consideration of the sub Committee to examine the case verification documents submitted by the applicant and recommend to GEAC the suitability of the hybrid for the North Zone.

**4.40 Permission for large scale trials and seed production of Chetana BG II, Rukmini BG II and Ram BG II with Cry X (Cry 1 Ac + Cry 2 Ab) by M/s. Emergent Genetics India Pvt. Ltd.**

1. The Committee noted that the present request is for direct entry into GEAC large-scale trials of those hybrids, which have not been approved by GEAC, and therefore the 'case verification' would not be applicable in such case. The Committee therefore rejected the request and directed the applicant to approach RCGM for conduct of multi-locational trials.

## D. Pharmaceuticals

### **4.41 Permission for import of small batch of Pegvisomant for clinical trials by M/s. Pfizer Ltd from U.K./USA.**

1. In the light of recommendations made by the Expert and DCGI, the Committee accorded approval for limited import of the product for conduct of phase-II clinical trials in India.

### **4.42 Import of Finase PC enzyme for formulation and marketing in India by M/s Textan Chemicals (P) Ltd. from Germany.**

1. The Committee was of the view that the specific comments of the Expert and the Department of Animal Husbandry may be obtained before the next GEAC meeting and the proposal be placed for consideration of the GEAC. Decision on the proposal was therefore deferred.

### **4.43 Permission for human insulin detemir by M/s. Novonordisk, Bangalore from Novonordisk Denmark.**

1. In the light of the recommendation made by the Expert Member and DCGI, the Committee accorded approval for import and marketing of the product in India subject to DCGI clearance.

### **4.44 Permission for manufacture and marketing of r-human epidermal growth factor by M/s Bharat Biotech International Ltd.**

1. The Committee after due consideration of the views expressed by the Expert approved the request for manufacture and marketing of r-human epidermal growth in India.

### **4.45 Permission for import and marketing of r-human insulin Glulisine APIDRA by M/s Aventis Pharma Ltd. Mumbai, from Aventis Pharma, Deutschland Germany.**

1. The Committee was of the view that the specific comments of DBT and clarifications sought by the Expert may be obtained before the next GEAC meeting and the proposal be placed for consideration of the GEAC. Decision on the proposal was therefore deferred.

### **4.46 Permission for import and marketing of r-Leish-111 f by M/s Institute of Medical Sciences, BHU from USA.**

1. The Committee was of the view that the specific comments of DBT, DCGI and the Experts may be obtained before the next GEAC meeting and the proposal be placed for consideration of the GEAC. Decision on the proposal was therefore deferred.



the sub-Committee will submit its recommendation to the GEAC before the next meeting.

2. As suggested by the Expert Member, DBT it was agreed that the names of the hybrids should be affixed with the name of the gene and event.

**Date of the Next GEAC Meeting:** The next GEAC meeting would be held on 3<sup>rd</sup> May 2005.

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