

## **Decisions taken in the 52<sup>nd</sup> Meeting of the Genetic Engineering Approval Committee (GEAC) held on 4<sup>th</sup> March 2005.**

The 52<sup>nd</sup> Meeting of the Genetic Engineering Approval Committee was held on 4<sup>th</sup> March 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 Center for Sustainable Agriculture & State Government of Punjab and given an opportunity to present their views and experience with Bt Cotton. The Committee also considered the representations received from Bharat Krishak Samaj & Greenpeace.

### **DECISIONS**

#### **A. Transgenic crops (commercial release)**

##### **1.0 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 noted that GEAC in its 32<sup>nd</sup> meeting held on 26.3.2002 had approved three Bt cotton varieties namely- MECH – 12 Bt, MECH – 162 Bt, and MECH - 184 Bt containing cry 1 A(c) gene MON 531 developed by Mahyco for commercial cultivation for a period of three years subject to compliance of certain conditions. Since the validity of the clearance expires in April 2005, the company has approached the GEAC for renewal of the GEAC clearance date 5<sup>th</sup> April 2002.

2. The Committee gave an opportunity to M/s Mahyco for presenting their case. The representatives of M/s Mahyco made a presentation on their experience with respect to performance of Bt Cotton and action taken on the compliance. To a query on whether the Bt variety is resistant to bollworm complex or only effective against American Bollworm it was clarified that Bt cotton is tolerant to Bollworm and not resistant. Over the period of approval good control of spotted bollworm as well as pink bollworm has been observed. However, as Bt cotton is not resistant there is a need to undertake sprays if the ETL level has been reached.

3. On the issue of higher yield obtained in Bt cotton, it was clarified that Bt cotton gives higher yield due to savings in the yield loss occurring because of bollworm damage. Though the higher yields are in a broad range, the average increase in the range of 29-30% over the non-Bt cotton hybrids has been observed during the period of approval.

4. Regarding the failure of Bt cotton crop in Andhra Pradesh and Government's directive to the company to pay compensation, it was clarified that the performance of Bt cotton has been satisfactory in the state of Andhra Pradesh. This is reflected in the total area coverage over the last few years. The sale of Bt cottonseed over the period of approval has increased from 2853 acres in the year 2000 to an area of 28070 acres in 2004 and is expected to further increase to 100000 acres in Kharif 2005. Regarding the compensation issue, the company would be responsible for factors, which can be attributed to its product as per the

MOU, and they cannot be held responsible for other extraneous factors outside its control. The Company further informed that appropriate steps have been taken by them to respond to the request for compensation.

5. To a query as to why the sale in Tamilnadu is lower in 2004 over the previous years, it was stated that the sales are lower due to drought conditions prevailing during the sowing period. The Company was also requested to comment on the deleterious soil effect because of Bt cotton use. It was stated that they have not seen the report and would not be able to comment at this stage. However extensive tests have been done by the Company to find out the effect on soil and in all the studies no adverse effects have been reported. Studies have been conducted by Mahyco for three years (2000-2002) in different districts of Andhra Pradesh (Adilabad, Medak, Warangal and Nalgonda). Regarding the lower yield of MECH-162 during the trials in Karnataka state, it was clarified that the expression of low /high yield is a function of many more factors beside the germplasm.

6. After detailed deliberation, the Committee noted that, on the various issues raised by NGOs, most of the issues were relating to Warangal District. The Committee further noted that agriculture is a State subject and no adverse reports on the performance of Bt cotton have been received from any of the State Governments in the six states where Bt cotton is under cultivation. However, before taking a final view, the Committee opined that views of the State Government of Andhra Pradesh need to be obtained, especially on the allegation made by Greenpeace regarding the doctoring of the yield data at Narasampet mandal in Warangal district. It was agreed that a time frame of three weeks may be given to AP Government for clarifying the above issue and the proposal may be placed before the GEAC in the next meeting for taking a final view.

**2.0 Permission for commercialization of A-651 Bt. and A-2534 Bt. with Cry 1 Ac gene in the North Zone and bulk Seed production by M/s Ankur Seeds Ltd.**

**&**

**3.0 Permission for commercialization of MRC –6301 Bt and MRC–6304 Bt with Cry 1 Ac gene in the North Zone by M/s Mahyco.**

**&**

**4.0 Permission for commercialization of RCH – 134 Bt and RCH - 317 Bt in the North Zone by M/s Rasi Seeds.**

1. The Committee noted that these companies have transferred their proprietary Bt. Cotton hybrids (Ankur 651 Bt, Ankur 2534Bt. MRC 6301 Bt , MRC 6304 Bt , RCH 134 Bt and RCH 317 Bt ) with cry 1 Ac gene (Mon 531 event ) along with gene cassette through traditional back crossing method. Of the six hybrids under consideration, the Department of Agriculture and Co-operation of Ministry of Agriculture have notified Ankur –651 on 1.1.1996.

2. The Member Secretary informed that the GEAC in its 41<sup>st</sup> meeting held on 15.4.2004 had accorded approval for conduct of large Scale trials of the six hybrids in the North Zone at 80 representative locations per genotype per zone based on the findings of the contained field trials and recommendations made by MEC and RCGM. As requested by GEAC the large-scale field has been evaluated by the MEC. The MEC in its meeting held on 18.1.2005 has recommended that the above hybrids be considered for commercial cultivation in the North

Zone. The MEC has also stated that these hybrids are resistance to CLCV and very much fit in the desired cotton cultivation practiced in the North Zone.

3. The Committee also took into consideration the results of the two year ICAR trials and recommendations by ICAR. The Committee noted that the incidence of the CLCV disease being higher at Sriganaganagar as compared to other locations, the data for this region may be taken into consideration as a worst case scenario. The Committee deliberated at length the issue of CLCV in North region and concluded that both in terms of yield and resistance to CLCV, the six hybrids under consideration were superior to the local check and its respective non-Bt counterpart.

4. While discussing the proposals, the Committee deliberated on the need or otherwise for two years of large-scale trials under GEAC for notified/un-notified varieties. The Member Secretary clarified that this issue was discussed while according approvals for large scale trials in Kharif 2004 wherein the view taken was that one year of large scale trials was adequate for notified varieties, however for un notified varieties, the need for second year trials would be based on the results of the first year trials. Further to ensure that various agro-climatic zones are represented adequately, the number of large-scale trials was increased to 80 locations/genotype per zone. No specific stipulations for 2 years of trials was stipulated by GEAC. In view of the above and taking into consideration the results of large scale trials, recommendation of MEC and results of 2 year ICAR trials, the Committee concluded that one year of large scale trials under GEAC is adequate in the case.

5. After detailed deliberations and taking into consideration the recommendation of MEC and results of ICAR trials the GEAC accorded approval for commercial cultivation of **Ankur 651 Bt, Ankur 2534Bt, MRC 6301 Bt, MRC 6304 Bt, RCH 134 Bt and RCH 317 Bt** for the North zone (Punjab, Haryana and Rajasthan) for a period of 2 years subject to the following conditions:-

- a. The applicant should look for the incidence of sucking pests on these hybrids and carry out artificial screening for CLCV resistance.
- b. The post release monitoring with specific reference to CLCV should be carried out by the State Department of Agriculture through the State Agriculture Universities and results of Kharif 2005 should be placed before the GEAC for further evaluation before the hybrids are taken up for commercial cultivation for the second year (Kharif 2006).

**B. Transgenic crops (Large scale trials subsequent to RCGM trials and MEC Evaluation)**

5.0 **Permission for large scale field trial of MRC 6025 BG- 1 and MRC-6029 BG I with Cry 1 Ac gene and seed production in the North Zone by M/s Mahyco.**

**&**

6.0 **Request for large-scale trials of RCH 314 Bt and RCH 308 Bt with Cry 1 Ac gene in the North Zone and seed production by M/s Rasi Seeds Pvt. Limited .**

**&**

## **7.0 Permission for large-scale trials of NCS –138, NCS-570 and NCS –913 with Cry 1 Ac gene and seed production in North Zone by M/s. Nuziveedu seeds Ltd.**

1. These companies have transferred their proprietary Bt. Cotton hybrids with cry 1 Ac gene (Mon 531 event ) along with gene cassette through traditional back crossing method.

2. The Companies have conducted multi-locational trials under RCGM during Kharif 2004. Out of the seven hybrids under consideration, the MEC in its meeting held on 18.1.2005 has recommended only six hybrids namely MRC 6025 BG-I , MRC 6029 BG-I , RCH 314 Bt, RCH 308 Bt , NCS 138, and NCS 913 for large-scale trials in the North Zone.

3. The Committee noted that above hybrids have undergone one year of ICAR trials under AICCIP during kharif 2004. However results of two years of ICAR trials is a requirement for commercials release.

4. The Committee noted that the hybrids under consideration have fulfilled the following requirements for its consideration for large scale field trials.

- Completion of Multi-locational field trials under RCGM
- Monitoring & Evaluation of the multi-locational trials by MEC
- Recommendation of MEC & RCGM on suitability of the hybrids for the North zone.

5. In view of the above stated facts and noting the findings of the contained field trials the GEAC approved large scale trials of **MRC 6025 BG-I , MRC 6029 BG-I , RCH 314 Bt, RCH 308 Bt, NCS 138 and NCS 913** at 80 representative locations per genotype per zone and seed production in an area of 100 ha 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 CLCuV.
- c) Until an alternate mechanism for monitoring of large scale trials is established, these trials may be monitored by the MEC.

## **8.0 Permission for large scale trials of MRC-7017 BG-II , BG - 7025 BG – II and MRC – 7031-BGII containing Cry X gene (s) (Cry 1 Ac & Cry 2 Ab) in the North Zone & seed production by M/s Mahyco.**

1. The Company has conducted multi-locational trials under RCGM during Kharif 2004. These trials have been evaluated by the MEC. Out of the three hybrids under consideration, the MEC in its meeting held on 18.1.2005 has recommended only MRC-7017 BG-II and MRC – 7031-BGII for large-scale trials in the North Zone. The MEC has also desired that the applicant should look for the incidence of sucking pests on these hybrids during large-scale trials and also artificial screening for CLCV resistance. The Committee was of the view that the recommendation of MEC should be applicable for all hybrids approved for the North zone.

2. The Committee noted that the hybrids under consideration have fulfilled the following requirements for its consideration for large scale field trials.

- Completion of Multi-locational field trials under RCGM
- Monitoring & Evaluation of the multi-locational trials by MEC
- Recommendation of MEC & RCGM on suitability of the hybrids for the North zone

3. In view of the above stated facts and noting the findings of the contained field trials and recommendation of MEC, the GEAC approved large scale trials of **MRC-7017 BG-II and MRC – 7031-BGII** at 80 representative locations per genotype per zone, ICAR trials and seed production in an area of 50 ha for each variety subject to 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 CLCuV.
- c) Until an alternate mechanism for monitoring of large scale trials is established, these trials may be monitored by the MEC

### C. Transgenic crops (Direct GEAC Large scale trials)

- 9.0 Permission for large-scale trials of ACH – 11 - 1 and ACH-155-1 with Cry 1 Ac gene in the North Zone by M/s Ajeet Seeds.
- &
- 10.0 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.
- &
- 11.0 Permission for large scale trials of Ankur-2226 BG, Sita BG, Ankur 1286 BG and Jassi BG with Cry 1 Ac gene in the North Zone and seed production by M/s. Ankur Seeds.
- &
- 12.0 Permission of large-scale trials GK 206 Bt, GK- 207 Bt, GK-210 Bt with Cry 1Ac gene in the North Zone and seed production by M/s G.K. Seeds Pvt. Ltd.
- &
- 13.0 Permission for large-scale trials of BG I with Cry 1Ac gene in the North Zone and seed production by Krishidhan Seeds Ltd.

1. The Committee noted that these companies have transferred their proprietary Bt. Cotton hybrids with cry 1 Ac gene (Mon 531 event) along with gene cassette through traditional back crossing method. The present request is for direct entry into the GEAC large-scale trials.

2. The Member Secretary informed that the basis for this request is linked to the decision taken in the RCGM meeting held on 13<sup>th</sup> May 2004, wherein it was decided that Bt cotton hybrids containing Cry 1 Ac gene MON 531 event need not go to the RCGM for clearance regarding conduct of multi-locational field trials as the event has already been evaluated for its biosafety with diverse tests and the applicant should directly approach GEAC and ICAR for conduct of large scale trials and ICAR trials. In view of the decision

taken by RCGM, the GEAC had taken a view that the hybrids may go for direct large-scale trials subject to the following case verification:

- Evidence that the same gene or its equivalent has been used.
- Measurement on the level of protein expression to confirm that the protein expression level is the same as that in the originally released variety.
- Evidence that transgenic variety is equivalent to the corresponding non-transgenic variety -Bt hybrids in the form of DNA fingerprinting.

3. After detailed deliberation, the Committee was of the view that none of the above companies have fulfilled the criteria of 'case verification' as enumerated in para 3 above and therefore their request cannot be considered. Further, no preliminary tests have been conducted to verify the suitability of these hybrids in terms of its early maturity and resistance to CLCV for the northern region. The Committee, therefore, concluded that the proposals are pre-mature for consideration for large scale trials.

#### **14.0 Permission for large scale trial of BCHH - 6317 - 2 BG II containing Cry X gene (s) (Cry 1 Ac & Cry 2 Ab) of Bt cotton hybrids for North Zone by Bioseed Research India Pvt. Ltd.**

1. M/s. Bioseeds Research India Pvt. Ltd is a sub-licensee of Mahyco and has transformed their propriety Bt cotton hybrid with Cry X (Cry 1 Ac and Cry I Ab) gene along with gene cassette through traditional back crossing.

2. The Committee noted that multi-locational trials under RCGM have not been conducted and the present request is for direct entry into the large-scale trials under GEAC.

3. The Committee noted that the RCGM decision dated 13.5.2005 is only for approved events and therefore the criteria for direct entry into large-scale trials through 'case verification' would not be applicable in this case. The Committee therefore directed the applicant to approach RCGM for conduct of multi-locational trials. The Committee concluded that after evaluation of the contained trials by the MEC and RCGM the matter may be considered at the appropriate stage. Hence the GEAC rejected the request of the company.

### **B-PHARMACEUTICALS**

#### **15.0 Permission to develop formulation and marketing of r- Human Insulin from Biocon by M/s USV Ltd. Mumbai.**

1. The Committee noted that the present application dated 20.1.2005 is for preparation of formulation of r-insulin from the bulk procured from M/s Biocon. The r-insulin developed by M/s. Biocon India Ltd. has been approved for manufacture and marketing of the product in India by the GEAC in its meeting held on 14.7.2004 after evaluation of the phase III clinical trials data. The product has also been approved by DCGI.

2. The GEAC approved the request of the company.

**16.0 Revalidation of GEAC permission for Import and Marketing of Recombinant Human Growth Hormone (SAIZEN) by M/s Serum Institute of India Ltd.**

1. The Committee noted that the GEAC in its 15<sup>th</sup> meeting held on 4.11.1997 had approved the import and marketing of the drug SAIZEN (r-Human Growth Hormone) from M/s Laboratories Serono, Switzerland. Subsequently permission for revalidation for another two years was accorded by GEAC in its 35<sup>th</sup> Meeting held on 7.3.2003.
2. The Committee conveyed their 'No Objection' for revalidation of the GEAC approval.

**17.0 Revalidation of GEAC permission for Import and Marketing of Recombinant Human Follicle Stimulating Hormone (follitropin alpha) Gonal-F by Serum Institute of India Ltd.**

1. The Committee noted that the GEAC in its 15<sup>th</sup> meeting held on 4<sup>th</sup> November 1997 had approved the import and marketing of the drug Gonal -F (r-Human Follicle stimulating Hormone) from M/s. Ares Serono, Switzerland. Subsequently permission for revalidation for another two years was accorded by GEAC in its 35<sup>th</sup> Meeting held 7.3.2003.
2. The Committee conveyed their 'No Objection' for revalidation of the GEAC approval.

**18.0 Permission for manufacture and marketing of r-human Epidermal Growth factor by M/S Bharat Biotech International Ltd. Hyderabad.**

1. The Committee noted that the above proposal was considered by the GEAC in its meeting 10.2.2005. The Member Secretary informed that the revised clarification submitted by the Company has been circulated to the Expert for the comments. The Committee was of the view that the specific comments of the Expert may be obtained before the next GEAC meeting for consideration of the proposal.

**Date of the Next GEAC Meeting: The next GEAC meeting would be held on 13<sup>th</sup> April 2005.**

\*\*\*\*\*

