

Decisions taken in the 68th Meeting of the Genetic Engineering Approval Committee held on 22.05.2006.

The 68th Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 1.6.2006 in the Ministry of Environment and Forests under the Chairmanship of Shri B S Parsheera Additional Secretary, MoEF and Chairman GEAC.

1.0 Consideration of Proposals

1.1 Permission for multi-locational trials recommended by RCGM in its meeting held on 23.5.2006.

1. In compliance with the Hon'ble Supreme Court Order dated 1.5.2006 in respect of WP NO 260/2005 – Aruna Rodrigues & Others vs Union of India, the Committee considered the recommendations made by RCGM on the 25 applications for conduct of multi-location field trials on transgenic crops in its meeting held on 23.5.2006.
2. After careful and in-depth consideration of the proposals and the recommendations of RCGM, the GEAC approved the proposals recommended by RCGM in the meeting held on 23.5.2006 and authorized Member Secretary, RCGM to issue the requisite communications in this regard.
3. During the deliberations, RCGM was advised to stipulate a condition requiring the Applicants to provide details of locations where it would undertake multi-location field trials within 30 days of issue of the clearance letter to the GEAC/RCGM/ State Department of Agriculture/ State Agricultural Universities. Both Member Secretaries GEAC and RCGM informed the Committee that approvals for field trials/ commercial release accorded by the GEAC/RCGM are communicated to the Secretary State Department of Agriculture of each State without any exception. However, the information from the State department does not percolate to the district level and field level functionaries in proper time and this gap is projected by the NGOS as lack of transparency or intentional withholding of information. The Chairman GEAC opined that this gap needs to be addressed on a priority basis and informed the Committee that the matter may be taken up with the respective State Govts through a D.O. letter..

1.2 Permission for large scale trials and seed production of seven Bt Brinjal hybrids namely MHB-4 Bt, MHB 9 Bt, MHB 10 Bt, MHB 80 Bt and MHB-99 Bt, MHB 11 Bt and MHB 39 Bt expressing cry 1 Ac gene.

1. M/s Mahyco has produced transgenic brinjal plants with cry 1Ac gene from *Bacillus thuringiensis* tolerant to the fruit and shoot borer, one of the major pests which attack the brinjal crop throughout its life cycle. This gene had been obtained as per the permit dated 16.3.2006 from the DBT. This gene was used to transform the proprietary brinjal line through Agro-bacterium –mediated transformation. The gene was then transferred into other Mahyco brinjal proprietary lines through traditional backcrossing method.
2. The Committee considered the application for large scale trials and seed production of Bt Brinjal hybrids namely MHB-4 Bt, MHB 9 Bt, MHB 10 Bt, MHB 80 Bt, MHB-99 Bt, MHB-11 Bt and MHB -39 Bt containing cry 1 Ac gene submitted by M/s Mahyco. The Member Secretary briefed the Committee on the deliberations and decision taken in the previous GEAC meeting held on 22.5.2006. She informed the Committee that a brief background note on the development of Bt Brinjal and presentation made by the Company in the previous meeting has been posted on MoEF website on 29.5.2006.

3. The Committee also considered the representations received from Centre for Sustainable Agriculture, Greenpeace, several civil society groups and individuals and noted their demand for posting the biosafety data on MoEF for 90 days for feedback on the findings of the biosafety tests prior to approving large scale trials of Bt Brinjal.

4. The Committee also deliberated at length on the protocol proposed for LST and noted that trials at 20 locations of seven hybrids are too large a number. The Committee suggested that the trials may be done only at 10 locations for each hybrid so that proper control and effective monitoring can be exercised. The Committee also opined that an isolation distance of 200 m should be maintained while conducting the field trials. The Committee further opined that the large scale field trials should be conducted with the full knowledge and involvement of Gram Sabha, District Magistrate and Block Development Officer. The issue of technical support to the Gram Sabha was also discussed. It was clarified that the involvement of Gram Sabha is to address social issues and apprehensions expressed by NGOs regarding sale of unapproved varieties, maintenance of isolation distance, awareness on biosafety issues etc. The technical support for monitoring and evaluating the field trials would be provided by the SAUs. The Committee recommended a five member monitoring team, comprising of nominees of Head of Department of Horticulture / Vegetable breeding, Commissioner/ Director of Agriculture, Representative of GEAC, Representative of DBT and Representative of ICAR or its nominee. The large scale field trials would be monitored twice.

5. The Committee also considered the views expressed by the Expert Members in the previous GEAC meeting and recommended that the following additional studies may be undertaken by the Company in tandem with the large scale field trials.

- a. Foliage toxicity study in Goats.
- b. Analysis of fruit dry matter to determine differences in yield from the agronomic trials in respect of Bt and check entries.
- c. Bt brinjal being a food crop, a flavour analysis of Bt and non-Bt fruits.
- d. 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.

6. After detailed deliberation, it was decided that in the first instance the following information would be posted on MoEF website for 15 days from the day the information is posted on the website:

- List of biosafety studies undertaken by the Company and its protocol as approved by RCGM.
- Biosafety data generated in respect of each study.
- Proposed Protocol for LST and seed production.

7.0 The feedback received would be referred for further review to Experts and the consolidated comments would be placed for consideration of the GEAC in its subsequent meeting.

1.3 Permission for large scale trials and seed production with IT 925 Bt and IT 928 Bt expressing Cry 1 Ac gene (Mon 531 event) in the South zone by M/s Proagro Seeds Co. Pvt Ltd.

1. The Committee considered the request for conducting large scale field trials with IT 925 Bt and IT 928 Bt expressing Cry 1 Ac gene (Mon 531 event) in the South zone and noted that both MEC and RCGM have recommended the hybrid IT 925 as suitable for South zone.

2. After detailed deliberations and taking into consideration the findings of the multi-location trials and recommendations made by RCGM and MEC and in accordance with decisions taken in the previous GEAC meeting the committee approved IT 925 for LST at 40 locations in the South Zone and 100 ha seed production.

1.4 Permission for large scale trials and seed production with Navkar 5 expressing encoding fusion genes (cry 1Ab+Cry Ac) ` GFM in the North, Central and South zones by M/s Navkar Hybrids Seeds Pvt Ltd.

1. The Committee noted that the request for direct entry into large scale field trials was considered by the GEAC in its meeting held on 3rd May 2005 wherein it was decided to await the Gazette notification of Ministry of Agriculture notifying NAVKAR 5 as a centrally released variety. The Member Secretary informed that, subsequently the hybrid has been notified vide notification of MOA dated 25.4.2006.

2. The Committee had also decided to set up a two Member sub-committee comprising of Dr Akhilesh Tyagi and Dr P Anand Kumar to evaluate the case verification documents (confirmation of gene event, protein expression level and DNA finger printing). The Chairman invited Dr Anand Kumar to give his views on the information furnished by the Company. It was stated that the information is in order. However the Company may be advised to submit the MOU signed with M/s Nath Seeds for transfer of Bt technology and copy of Southern blot for Navkar 5 Bt hybrid. Subject to submission of the above documents, the Committee approved LST and ICAR trials with Navkar 5 in the North, Central and South zones.

3. As per the prevailing practice only one year LST and one year ICAR trials are mandatory for notified varieties. Since Navkar 5 bt would fulfill this requirement during Kharif 2006, the Committee approved the request for 100 ha seed production.

1.5 Permission for 2nd large scale trials with ACH 155-1 Bt expressing Cry 1 Ac gene (Mon 531 event) by M/s Ajeet Seeds Ltd.

1. The Committee considered the request for conduct of second year LST with ACH 155-1 Bt containing Cry Ac gene (MON-531 event) in the South zone. It was noted that the field trials have been monitored by MEC. The MEC has recommended the hybrid for commercial release subject to completion of procedural requirement. The second year LST is being requested because the procedural requirement of two year ICAR trials has not been completed.

2. In view of the above stated facts, the GEAC approved the conduct of second year LST with ACH 155-1 Bt in the South zone at 40 locations during Kharif 2006 and seed production in an area of 100 ha.

1.6 Request for seed production in 100 ha during first year LST/MLT.

1. The Committee considered the request from several Companies for seed production in an area of 100 ha in light of the new procedure recommended by the sub Committee under Dr C D Mayee, Chairman ASRB and Co-Chair GEAC. The Committee noted that if the new procedure is adopted, several Companies would be at a disadvantage in view of the limited seed production permitted by GEAC. After detailed deliberation, the Committee recommended 100 ha seed production for all Bt cotton hybrids containing Cry 1 Ac gene (Mon 531 event) approved for LST by GEAC.

2. The request for seed production in an area of 100 ha in respect of RCH 2 BG-II and ACH 33-2 BG-II, both containing Cry 1Ac + Cry 2Ab gene (MON 15985 event) during first year LST was also considered by the Committee. It was noted that RCH 2 is a centrally notified variety and ACH 33-2

has been recommended by the Central Sub-Committee on Crop Standards, Notification and Release of varieties for Notification in its meeting held on 31.5.2006. As per the prevailing practice only one year LST and one year ICAR trials are mandatory for notified varieties. Since RCH 2 BG -II and ACH 33-2 BG-II would fulfill this requirement during Kharif 2006, the Committee approved the request for 100 ha seed production.

1.7 Representation received from Centre for Sustainable Agriculture regarding mortality in Sheep flocks after grazing on Bt Cotton field at Warangal Andhra Pradesh.

1. The Committee deliberated at length on the representation received from the Centre for Sustainable Agriculture regarding mortality in Sheep flocks after grazing on Bt Cotton field at Warangal, Andhra Pradesh. The general opinion was that the report appears to be highly exaggerated and is based more on hearsay than scientific facts. The Bt cotton released for commercial cultivation have been approved after evaluation of biosafety data which also includes feed studies. The 90 day animal feed studies conducted at ITRS, Lucknow, feeding studies conducted at G B Pant University of Agriculture, Pantnagar on lactating cows and on fish at Avian Research Institute, Izatnagar indicate no toxic effect.

2. The acute oral toxicity study of Bt protein in mice conducted at Agriculture Group/ Environmental Health laboratory, USA concludes that there was no treatment related adverse finding in any of the groups administered B.t.k. HD-73 protein by oral gavage at dosages up to 4200 mg/kg. The oral LD50 for B.t.k HD-73 protein in mice is greater than 4200 mg/kg and the no-observed effect level is 4200 mg/kg.

3. Further mice gavage studies have shown that an intake of 4300 mg Cry1Ac / Kg body wt. had no ill effect on the mice. Assuming a similar upper safe limit for goats, in order to have an intake of 4300 mg. of Cry1Ac / Kg of body wt., the goat should eat (assuming the goat weights 15 kgs) 24,339 kg of leaf / 50,300 kg of boll rind which is not practically feasible.

4. The Member Secretary RCGM informed that, the above representation was discussed in the RCGM meeting held on 23.5.2006 wherein it has been recommended that DBT may sponsor a study to assess the problem at Warangal District with the help of local Veterinary Hospital in the district. The Committee requested DBT to expedite the study so that the allegation made by the NGOs can be brought to a logical conclusion. The Committee also agreed that, in future, leaf toxicity studies need to be included as part of the biosafety studies. The Committee further decided to refer the matter to the State Department of Agriculture for a factual report on the allegation made by the NGOs and the findings of the post mortem report.

1.8 Permission of GEAC for sale of Bt cotton hybrids under different brand names.

1. The request of M/s Rasi Seeds and M/s Nuziveedu for sale of their hybrids under different brand names was discussed.

2. After detailed deliberation the Committee opined that:

- A. The name/number of the hybrid as approved by the GEAC should be prominently displayed on the label and the trade name may be indicated in parenthesis.
- B. The parent Company who has obtained the approval of GEAC would be liable for any violation or misinformation under the provisions of EPA /Seed Act.
- C. In future, the Companies may indicate the different brand names under which they propose to sell the Bt cotton seeds in their original application itself.
- D. The matter being a State subject, the State Govt may take a final view on the issue taking into cognizance the provisions of the Trade Mark Act.

1.9 Permission for one year large scale trials and seed production in an area of 100 ha in respect of RCH 2 BG-II expressing cry 1 Ac and cry 2Ab (Event 15985) in the South Zone.

1. The request for one year LST and seed production in an area of 100 ha in respect of RCH 2 BG-II expressing cry 1 Ac and cry 2Ab (Event 15985) during first year LST was also considered by the Committee. It was noted that RCH 2 is a centrally notified variety. As per the prevailing practice only one year LST and one year ICAR trials are mandatory for notified varieties. Since RCH 2 BG -2 would fulfill this requirement during Kharif 2006, the Committee approved the request for one year LST and 100 ha seed production.

The date of the next GEAC meeting is scheduled for 12.7.2006
