## Decisions taken in the 55<sup>th</sup> Meeting of the Genetic Engineering Approval Committee (GEAC) held on 20 May 2005.

The 55<sup>th</sup> Meeting of the Genetic Engineering Approval Committee was held on 20<sup>th</sup> May 2005 at 2.30 AM in the Ministry of Environment and Forests under the Chairmanship of Shri Suresh Chandra, Special Secretary & Chairman GEAC.

## **Decisions**

- Before initiating discussion on the specific agenda items, the Member Secretary informed the Committee that a number of companies namely M/s Nath Seeds, M/s JK Seeds, M/s Emergent, Crop Life Association, Indian Seed Industry have represented against the GEAC decision of 3<sup>rd</sup> May 2005 to authorize large scale field trials for a period of two years and seed production in an area of 1 acre during the first year large scale trials and 20 acres during the second year. Since this issue is also relevant to agenda items 2 and 3 she requested the Chair that the matter be considered in this meeting. She explained that this decision has given rise to some anomalies and inconsistency in the GEAC decision with previous decisions. It was brought to the notice of the Committee, that from Kharif 2004 till May 2005 about 13 hybrids have been approved for commercial release based on one-year large-scale trials at 80 locations per zone. Only in cases where the hybrids were tested at locations less than 80 were asked to repeat the large-scale trials for the second year. It was in this context the GEAC in its 41st meeting had taken a view that all hybrids will be tested at 80 locations per zone so as to avoid any inconsistency in the decision-making. On the other hand in the same meeting of 3.5.2005, the GEAC has approved 6 Bt hybrids based on one-year large-scale trial data.
- 2. The Chairman initiated the discussion and requested the Committee to look for a solution to remove any inconsistency in the GEAC decision. Some Members expressed the view that since Cry I AC gene (MON 531 event) has been evaluated for its biosafety and approved for commercial release, one year of large-scale trials is adequate to test the agronomic performance of the hybrid and its suitability for the region. One of the Expert members pointed out, however, that a number of hybrids were released based on one-year trials to meet the demands for Bt cottonseeds and curb the sale of illegal seeds. However, in future facilitating release of Bt cotton without two year testing is not desirable scientifically especially when the ICAR trial data show great variance between the yield data of Bt and non-Bt varieties. After detailed deliberations and taking into consideration the need for removing the anomaly in the decision and for maintaining consistency it was decided that the earlier direction of the GEAC to conduct two years of trials in case of approved event may be amended as follows:

"The large scale trials will be conducted during Kharif 2005 and data submitted to the GEAC along with the recommendations of MEC for enabling the Committee to take a view on the necessity for further trials or otherwise".

The substantive issue of one year or two years of GEAC trials and seed production in case of approved events in un-notified varieties may be referred to a sub- Committee.

3. The issue of limited seed production in an area of 1 acre was also discussed. In view of the revised decision, it was felt that unless there is availability of seed the applicant cannot go for commercial release even if it is approved by the GEAC. After detailed

deliberations it was decided that seed production may be permitted in an area up to 20 acres wherever permission has been given for one year trials.

- 4. The Committee agreed that the above decisions 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. This is consistent with the recommendations of the Swaminathan Committee report.
- 5. The Committee authorized the Chairman to set up the sub Committee to submit recommendations on the substantive issues as mentioned in para 2.

## Agenda Item

- Permission for commercial release of Bt cotton hybrids NCS-145, 'Bunny' Bt and NCS –207 'Mallika' Bt for Central & South Zones by M/s Nuziveedu Seeds Ltd.
- 1. The Committee noted that ICAR, on the basis of recommendation of the Swaminathan Committee report, has decided that for centrally notified variety only one year of ICAR trials is necessary. ICAR based on the results of the first year AICCIP trials have recommended NCS-145, 'Bunny' Bt and NCS –207 'Mallika' Bt containing cry 1 Ac gene (MON 531 event) for commercial release.
- 2. The Committee also noted that on the basis of the DNA fingerprinting the sub-Committee concluded that the DNA Fingerprinting data provided by the applicant is indicative of the high degree of similarity in genetic makeup of Bt. cotton hybrids NCS-145 "Bunny" and NCS-207 "Mallika" to their non-Bt. cotton hybrids.
- 3. The Committee also noted the recommendations of the sub Committee to further refine the DNA fingerprinting data with the help of tools and techniques developed at NBPGR/NRCPB, New Delhi. On this matter it was clarified that the tools for DNA finger printing is evolving and the recommendation has been made with a view to adopt more refined techniques. It was also suggested that there is a need for developing guidelines and protocols for DNA fingerprinting.
- 4. After detailed deliberations on the basis of the recommendations received from MEC, ICAR and the sub Committee constituted by the GEAC for evaluating the case verification criteria and taking into consideration that NCS-145, 'Bunny' Bt and NCS –207 'Mallika' Bt are centrally notified varieties, the GEAC approved commercial release of NCS-145, 'Bunny' Bt and NCS –207 'Mallika' Bt for a period of three years.
- 2. Permission for large-scale trials of ACH 155-1 and seed production by M/s Ajeet Seeds in the South Zone.
- 1. After detailed deliberations and taking into consideration the findings of the mulit-location trials and recommendations made by RCGM and MEC the Committee approved the large scale trials of ACH 155-1 Bt containing MON 531 event at 80 locations in the South Zone as per the protocol recommended by the sub-committee constituted by the GEAC. The large scale trials will be conducted during Kharif 2005 and data submitted to the GEAC along with the recommendations of MEC for enabling the Committee to take a view on the necessity for further trials or otherwise.

- 2. On the request of the Company for seed production of the above cotton hybrid in an area of 50 ha it was decided permit seed production in an area of 20 acres only.
- 3. Permission for large scale field trials and seed production of MRC-6355 BG-I for Central & South Zones by M/s Mahyco.
- 1. After detailed deliberations and taking into consideration the findings of the mulit-location trials and recommendations made by RCGM and MEC the Committee approved the large scale trials of MRC 6355 BG-1 containing MON 531 event at 80 locations in the Central & South Zone as per the protocol recommended by the sub Committee constituted by the GEAC. The large scale trials will be conducted during Kharif 2005 and data submitted to the GEAC along with the recommendations of MEC for enabling the Committee to take a view on the necessity for further trials or otherwise.
- 2. On the request of the Company for seed production of the above cotton hybrid in an area of 100 ha it was decided to permit seed production in an area of 20 acres only.
- 4. Permission for seed production of MRC-7341 BG-II, MRC-7347 BG-II and MRC-7351 BG-II for Central & South Zone by M/s Mahyco.
- 1. The Committee noted that BG-II is not an approved event and therefore would require 2 years of large-scale trials. The GEAC in its previous meeting has approved large-scale trials of MRC 7341 BG-II, MRC 7347 BG-II and MRC 7351 BG-II in the Central Zone and MRC 7347, BG-II and MRC 7351 BG-II in the South Zone. In accordance with the decision taken in the previous meeting, the company has been granted seed production in an area of 1 acre during the fist year large-scale trials. The Committee concluded that the request does not merit consideration.

It was decided that the next GEAC meeting will be held as per the schedule on 8<sup>th</sup> June 2005.

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