

## **Decision taken in the 75<sup>th</sup> Meeting of the Genetic Engineering Approval Committee held on 14.3.2007**

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The 75<sup>th</sup> Meeting of the Genetic Engineering Approval Committee (GEAC) was held on 14.3.2007 at 11.00 AM in Room No. 624 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**

The Member-Secretary, briefed the Committee on the following aspects:

- a) The new procedure for commercial release of Bt cotton adopted by the GEAC based on the recommendations of the Sub Committee under Dr. C. D. Mayee, Chairman, ASRB and Co-Chair, GEAC in the meeting held on 30.06.2006. The Member-Secretary, RCGM sought clarification in respect of the following anomalies arising from adoption of the new procedure:
  - i) As per the new procedure, in respect of Bt cotton hybrids expressing Cry 1Ac MON 531 event MEC is required to evaluate only MLT and SAU trials data. However, many of the Seed Companies have completed LST and ICAR trials during Kharif 2006. The results of the LST and ICAR trials have not been evaluated by the MEC and the Companies were directed to submit the LST data directly to the GEAC. However, Agenda items 4.5 and 4.7 to 4.111 indicate that some of the hybrids have not fulfilled the regulatory requirement as the LST data has not been evaluated by MEC. Member Secretary, GEAC clarified that prior to adoption of the Sub Committee report, the GEAC had approved large scale trials and ICAR trials of Bt cotton during Kharif 2006. The discrepancy arose because ICAR had accepted only one hybrid under the AICCIP trial. The remaining hybrids were tested under the SAU system. This situation would not arise in future. It was further informed that even in the past, the LST data was always submitted to MEC and not directly to GEAC. After detailed deliberation, the Committee concluded that in cases where the Companies have conducted LST and ICAR trial, the MEC may examine the data and submit their recommendations on the suitability of the hybrids for commercial release to the GEAC.
  - ii) In respect of Bt cotton hybrids expressing new gene / events the new procedure mandates conduct of two years of LST and two years of ICAR trials. However, some of the Companies have gone for SAU trials instead of ICAR trials on their own. The Committee was of the view that while additional data is welcome, only those applications which have completed the requisite LST and ICAR trials may be considered by the MEC.
  - iii) On the issue of whether two years of ICAR and two years of LST is mandatory for notified Bt cotton hybrids expressing new gene / events, it was clarified that in accordance with the policy decision taken by ICAR for notified varieties, only one year ICAR trials is mandatory. Accordingly, the earlier GEAC decision to synchronize the LST and ICAR trials for one year would be applicable for notified varieties.
- b) The directions issued by the Hon'ble Supreme Court vide order dated 22.09.2006 and 15.2.2007 in Writ Petition No. 260/2005 and IA No. 4/2006 filed by M/s Aruna Rodrigues vs. UoI. The Committee noted that Member-Secretary, GEAC and Member Secretary, RCGM had met the Additional Solicitor General, on 13.3.2007 to discuss the implications of the Hon'ble Supreme Court on approval for commercial release of Bt cotton hybrids expressing released gene event. The Additional Solicitor General (ASG) has advised that the Hon'ble Supreme Court in the Order dated 22.9.2006 has directed the GEAC "to withhold the approvals till

further directions are issued". In the wake of such a direction, there is a possibility that the Petitioners would file contempt petition in the event fresh approvals are granted for commercialization of the Bt cotton. Therefore, in the first instance, it would be appropriate to file a petition for the vacations/ modification of the order dated 22.09.2006 and pursuant thereto, grant fresh approvals. During the deliberations, the Committee requested Prof. Govindraj Hegde, National Law School to give his views on the implications of the Hon'ble Supreme Court order dated 22.9.2006. The Expert Member agreed with the views of the ASG. He, further, opined that the orders of the Hon'ble Supreme Court in no way prevents the GEAC from deliberating on the issues pending before it and undertaking its other functions. After detailed deliberations, the Committee was of the view that the results of the field trials on which there has been no injunction by the Hon'ble Supreme Court may be considered and merits of the case may be deliberated by the GEAC. However, decision on approvals may be deferred in compliance with the SC order. The Committee further opined, in view of the seasonality involved there is an urgent need to take timely decision on the release of Bt cotton in the interest of Indian farmers. The Committee was of the view that this issue may be brought to the notice of the Hon'ble Supreme Court.

- c) The recommendations of MEC/RCGM / ICAR on the applications received from 14 Companies for commercial release of Bt cotton hybrids in the North zone. The Committee noted that a total of 31 hybrids have been placed for consideration of the GEAC in this meeting.

The Committee considered the following proposals in light of the above deliberations:

**A. Bt cotton hybrids expressing *cry1Ac* gene (MON 531 event)**

- 1.1 **Permission for commercialization of Ankur 2226 BG, and Jassi BG with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Ankur Seeds Ltd.**  
&
- 1.2 **Permission for commercialization of PCH 917 Bt, PCH 306 Bt, and PCH 406 Bt with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Prabhat Agri Biotech Ltd**  
&
- 1.3 **Permission for commercialization of Sigma Bt and Ole Bt with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Vibha Agrotech Ltd.**  
&
- 1.4 **Permission for commercialization of SDS-405 Bt, SDS 1368 Bt, SDS 27 Bt, SDS 9 Bt SDS 234 Bt with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Nandi Seeds (P) Ltd.**  
&
- 1.5 **Permission for commercialization of NCS 918 Bt, NCS-950 Bt and NCS-951 Bt with *cry 1 Ac* gene (MON 531 event) in the North Zone by M/s Nuziveedu Seeds Ltd.**  
&
- 1.6 **Permission for commercialization of KDCHH-144 and KDCHH 9810 with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Krishidhan Seeds Ltd.**  
&
- 1.7 **Permission for commercialization of IT 905 BG I with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Proagro Seed Company Pvt. Ltd.**  
&
- 1.8 **Permission for commercialization of ACH-155-1 Bt. with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Ajeet Seeds Ltd.**  
&
- 1.9 **Permission for commercialization of NAMCOT-402 Bt, with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Namdhari Seeds (P) Ltd.**  
&

**1.10 Permission for commercialization of GK 206 Bt with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Ganga Kaveri Seeds Pvt. Ltd.**

&

**1.11 Permission for commercialization of 6317 Bt and 6488 Bt with *cry 1Ac* gene (MON 531 event) in the North Zone by M/s Bio seeds Research**

1.1.1 The recommendations of the MEC/RCGM/ICAR in respect of the 31 Bt cotton hybrids expressing Cry 1Ac gene (MON 531 event) referred in Agenda Items 4.1 to 4.11 was placed before the Committee. The Committee noted that MEC has recommended the commercial release of eight hybrids namely Ankur 2226 BG, PCH 406 Bt, Sigma Bt and Ole Bt, SDS 1368 Bt, SDS 9 Bt, NCS 950 Bt and KDCHH 9810 Bt. During the deliberations it was noted that the MEC recommendations is based on the MLT/SAU data only. Chairman, MEC clarified that the case verification criteria recommended by the Sub Committee on Bt cotton and related issues, has not been submitted to the MEC. The Committee further noted that subsequent to the adoption of the Sub Committee report, a specific proforma for submission of information related to Bt cotton hybrids expressing MON 531 event was designed and Member Secretary, RCGM was requested to communicate the same to all the Seed Industries. The Committee further opined that information related to integration of the gene, protein expression etc are vital to assess the performance of the hybrid. After detailed deliberations the Committee requested Chairman, MEC along with a Sub Committee comprising of MEC members to re-examine the proposals taking into consideration the following aspects and submit its recommendations for reconsideration of the RCGM/GEAC:

- i) Case verification data and other information as per the requisite proforma.
- ii) The state wise locations where SAU trials have been conducted.
- iii) Suitability of the hybrids for irrigated / un-irrigated areas
- iv) Cases where LST / ICAR trials have been conducted MEC may examine the merits of the case based on LST / ICAR data.

**B. Hybrids expressing stacked genes (*Cry 1AC & Cry 2Ab* (MON 15985))**

**1.12 Permission for commercialization of MRC 7017 BG II and MRC 7031 BG II with *cry 1Ac & cry 2 Ab* genes (Mon 15985) in the North Zone by M/s Mahyco Seeds Ltd.**

1.12.1 The Committee noted that both the hybrids have completed the required two year LST and two years of field testing under ICAR system. The Committee also noted that MEC in its meeting held on 22-23.1.2007 has recommended both the hybrids (**MRC 7017 BG II and MRC 7031 BG II**) for commercial release in the North Zone. The representative of ICAR informed that in terms of fibre quality and other parameters the hybrids are on par with the Bt check. However, in terms of seed cotton yield it was 17% less than the Bt check.

1.12.2 Decision on the proposal was deferred in light of the Hon'ble SC Order dated 22.9.2006 in WP 260/2005 and in IA No. 4/2006 filed by M/s Aruna Rodrigues vs UoI.

**1.13 Permission for commercialization of NCS 145 BG II with *cry 1Ac & cry 2Ab* (MON 15985) in the North Zone by M/s Nuziveedu Seeds Ltd.**

1.13.1 The Committee noted that NCS 145 being a centrally notified variety, has completed the mandatory requirement of one year LST and one year ICAR trial. The Committee also noted that the MEC in its meeting held on 22-23.1.2007 has recommended **NCS 145 BG II** for commercial release in the North Zone. The representative of ICAR informed that in terms of fibre quality and other parameters the hybrids are on par with the Bt check. However, in terms of seed cotton yield it was 30% less than the Bt check.

1.13.2 Decision on the proposal was deferred in light of the Hon'ble SC Order dated 22.9.2006 in WP 260/2005 and in IA No. 4/2006 filed by M/s Aruna Rodrigues vs UoI.

**1.14 Permission for commercialization of Tulasi 4 BG II with *cry 1Ac & cry 2Ab* (MON 15985) in the North Zone by M/s Tulasi Seeds Ltd.**

1.14.1 The Committee noted that Tulasi 4 BG II has completed only one year LST with the approval of the GEAC during kharif 2006. The hybrid has not been tested under the ICAR system. As per the regulatory requirement, the hybrid is required to complete two years of LST and two years of ICAR trials.

1.14.2 The Committee rejected the request.

**1.15 Permission for commercialization of ACH-33-2 BG II with *cry 1Ac & cry 2Ab* genes (MON 15985) in the North Zone by M/s Ajeet Seeds Ltd.**

1.15.1 The Committee noted that ACH-33-2 BG II being a centrally notified variety, has completed the mandatory requirement of one year LST and one year ICAR trial. However, the MEC in its meeting held on 22-23.1.2007 has recommended to conduct second year LST. During the deliberations the MEC Chairman, informed the Committee that MEC was not aware that ACH – 33-2 BG II has been notified. The Committee requested MEC to re-examine the proposal in light of the above information and submit their recommendation for reconsideration by the GEAC.

**1.16 Permission for Commercial release of KDCHH-441 (BG II) Bt cotton with *cry 1Ac & cry 2Ab* gene (MON 15985 event) for North zone by M/s. Krishidhan Seeds (P) Ltd**

1.16.1 The Committee noted that KDCHH 441 (BG II) has completed one year of LST and one year of testing under the ICAR system during Kharif 2006. As per the regulatory requirement, the hybrid is required to complete two years of LST and two years of ICAR trials. It was also noted that the MEC in its meeting held on 22-23.1.2007 has recommended to conduct second year LST.

1.16.2 The Committee rejected the request.

**C. Hybrids expressing (*cry 1Ac* event 1)**

**1.17 Permission for commercialization of JKCH 1050 Bt and JKCH 226 Bt with *cry 1Ac* event 1 in the North Zone by M/s J.K. Agri Genetics Ltd**

1.17.1 The Committee noted that the hybrid JKCH 1050 Bt has not completed two years of LST as per the regulatory requirement. In respect of JKCH 226 Bt, the hybrid has not undergone the mandatory large scale testing in the North Zone.

1.17.2 The Committee rejected the request.

**2.0 Other Items**

**2.1 Supreme Court Directions dated 15.2.2007 in WP 260/2005 & IA 4/2006 filed by M/s Aruna Rodrigues vs UOI.**

2.1.1 The Committee noted that Hon'ble Supreme Court vide its order dated 15.2.2007 has directed the Union of India to file a report within a period of six weeks stating therein as to what would be the implications and biological results of ongoing field trials. On the action taken to file the UoI response, the Member Secretary GEAC informed that during the period

between 1.5.2006 and 22.9.2006, the GEAC based on the recommendation of RCGM has approved 144 applications of which 90 applications are for MLT, 32 applications are for Experimental Seed Production, 18 applications are for Strip trials and 5 applications are for pollen flow studies. The crops approved for various trials are mainly Bt cotton (129 applications). The others include transgenic Okra, Cauliflower, Brinjal, Rice, Castor, Groundnut, Tomato and Potato. Information on the details of the trials (location, design and no of hybrids etc), results of the pollen flow studies conducted prior to MLT, MLT data and evaluation report / recommendations of MEC are under compilation. During the deliberations, the Committee noted that out of 129 Bt cotton under MLT, 122 are related to approved gene events which have been evaluated for its environmental and health safety prior to its release. It was suggested that the biosafety data dossier may be made available to the Hon'ble Supreme Court. In respect of Bt cotton expressing new gene events and other new GM crops under various stages of field trials, the Committee requested DBT to make available the requisite information related to pollen flow studies and MLT data expeditiously to the Member Secretary, GEAC. The Committee requested Member Secretary, GEAC to finalize the report for submission to the Hon'ble Supreme Court in consultation with the Member-Secretary, RCGM and Chairman, MEC.

## **2.2 Issues related to export of GM rice.**

2.2.1 The Committee noted and deliberated on the following suggestions made by the All India Rice Exporters Association (AIREA) in the meeting convened on 19.2.2007 by the Ministry of Commerce & Industry under the Chairmanship of **Joint Secretary** regarding the current crisis in EU over GM rice from USA and other sources and its impact on global rice trade.

- a) No open field trials to be held in the Basmati growing areas i.e. Haryana, Punjab, Western Uttar Pradesh and Uttarakhand.
- b) All trials should have a lead scientist's name with contact details who will be responsible for all aspects of the trials including regulatory requirements.
- c) Prior to start of the trials GEAC/RCGM should be advised for public information of a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination.
- d) All testing as required by stakeholders will be done free of cost by the company conducting the trial.
- e) Prior to start of the trials the company to deposit Rs. 5 crore that would be refunded to them once the:-
  - i) Trials have been completed
  - ii) Detections tests conducted all around the test field trials to confirm that no contamination has taken place
  - iii) Certificate from the monitoring committee confirming that all regulations have been complied with and all material has been accounted for.
  - iv) An affidavit from the lead scientist and the company confirming total and full compliance of all regulations and total containment.
- f) All Companies and Directors conducting the trial will remain and continue to be constructively liable for Acts of Omissions and Commissions with regard if the trials in addition to the lead scientist named inter alia for all damages caused to the environment or livelihood or health, business and reputation of the entities affected on account of trials.

After detailed deliberations, the Committee was of the view:

- a. The RCGM/GEAC have already taken a policy decision not to permit open field trials of GM rice in proximity to Basmati growing areas. The concerns expressed by AIREA in this regard have already been addressed.

- b. Member Secretary, Institutional Biosafety Committee should be made responsible for all aspects of the trials including regulatory requirements.
- c. Prior to bringing out the GM material from the green house for conduct of open field trials (Strip trials, MLT etc.) the Company should submit a validated event specific test protocol at an LOD of at least 0.01% to detect and confirm that there has been no contamination. It was agreed that the testing protocol should be available in the public domain. The Committee suggested that Directorate of Rice Research Institute and Private Laboratories such as Amar Diagnostics may be accredited as per the NABL accreditation system for the above purpose.
- d. The Committee agreed that all testing as required by stakeholders will be done by the company conducting the trial. However, on the suggestion that the cost for testing will be borne by the Company conducting the trial, the Committee was of the view that it is a matter to be negotiated between the Company and the Rice Exporters.
- e. The Committee did not agree on the suggestion regarding depositing Rs. 5 crores by the Company prior to conduct of trials and the proposed criteria for the amount. The Committee was of the view that no public institution would be in a position to undertake any research activity in the area of GM crops if such conditions are made mandatory. Further, in the absence of a national law on liability arising from GMOs, it may not be appropriate to stipulate a financial mechanism for redressal at this stage.
- f. The Committee agreed that the Company should be made liable for Acts of Omissions and Commissions. However, the suggestion needs to be re-phrased. The Committee requested Prof. G. Hegde, National law School, Bangalore to redraft the suggestion appropriately.

### **2.3 Amendments to Rule 13 of Rules, 1989 of EPA, 1986 regarding renewal of GEAC permission for transgenic crops.**

2.3.1 The Committee briefly discussed the requirement of renewal of all GEAC permissions every two years under Rule 13, para 2 of Rules, 1989. The Committee was of the view that in case of transgenic crops, renewal of GEAC permission after the second renewal may not be necessary as the hybrids are usually phased out after a period of four to five years with the entry of new and better hybrids / technology.

2.3.2 On the issue of amendment to Rule 13, the Committee was of the view that the need for amending the existing provision may be considered at a later stage when the proposals for renewal of GEAC permission are referred to the Committee after a period of three years.

### **2.4 Representation received from Centre for Sustainable Agriculture regarding Sheep mortality due to consumption Bt cotton leaves in Adilabad District in Andhra Pradesh.**

2.4.1 The Committee noted that the issue regarding sheep mortality due to consumption of Bt cotton leaves at Warangal was earlier discussed in the GEAC meetings held on 1.6.2006 and 12.8.2006 wherein the Committee had requested the State Government to submit a factual report on the allegations made by the NGOs and findings of the post mortem report. Member Secretary, GEAC informed that there has been no response from the State Government. The Committee had also requested DBT to sponsor a study to assess the problem at Warangal district with the help of local veterinary hospital. Member Secretary, RCGM informed that in the absence of any proposal from the concerned institutions no study has been initiated so far.

2.4.2 The Committee considered the representation received from Centre for Sustainable Agriculture and the public notice issued by the Joint Director, Animal Husbandry Department, Adilabad, Andhra Pradesh which reads as follows:

“It has come to our notice that in several blocks of the district, animals are falling sick after grazing on Bt cotton fields. After harvesting cotton completely from the fields, there is a long tradition in the district of grazing animals in those cotton fields. However, because Bt cotton is being grown in large tracts and because of a yet unidentified toxic material in these plants, it has come to our notice that animals which are grazing on these fields are exhibiting symptoms like shivers, convulsions, running nose, bloat, bloody diarrhea etc., and are dying. Therefore, we appeal to farmers not to graze their animals on Bt cotton fields. We request farmer brethren to please do approach the nearest veterinary doctor and get treatment, if any animal has grazed on such fields accidentally”.

2.4.3 The Committee was of the view that there is a need to conduct a scientific investigation on the matter. It was agreed that a fact finding team comprising of Director, IBRI or his nominee, Dean of Veterinary College, Andhra Pradesh, Joint Director, Department of Animal Husbandry, Andhra Pradesh and Dr. Nagaraju, Cotton Research Station, Andhra Pradesh may be deputed to examine the above issue and submit a factual report based on a site visit to Adilabad / Warangal districts of Andhra Pradesh and discussions with the farmers, local veterinary hospital as well as the State Government.

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