

Minutes of the 2nd Meeting of the Standing Committee to review applications for commercial release of Bt cotton hybrids expressing approved events under 'event based approval mechanism (EBAM) held on 15th May, 2009 in Room No. 727, DBT, New Delhi

The 2nd meeting of the Standing Committee to review applications for commercial release of Bt cotton hybrids expressing approved events under 'event based approval mechanism (EBAM)' was held on 15th May, 2009 in Room No.727, DBT, New Delhi under the Chairmanship of Dr. P. Balasubramanian, Director, Centre for Plant Molecular Biology (CPMB), TNAU, Coimbatore. The list of participants is enclosed at Annexure-1.

Welcome Remarks by the Chairman

Dr. Balasubramanian, Chairman, Standing Committee extended a formal welcome to all members of Standing Committee for the 2nd meeting and initiated the process of the meeting.

Leave of Absence

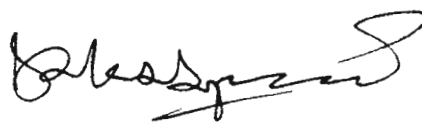
The Committee noted that Dr. K. R. Kranthi had requested for leave of absence due to Australian sojourn up till 19-5-2009. Leave of absence was granted to Dr. Kranthi.

Action taken report by the Member- Secretary

Member Secretary distributed the Action Taken Report of the 1st Standing Committee meeting held on 17.4.2009. It was informed by the Member-Secretary that the deferred applications of M/s. Prabhat Agrotech and M/s. Nuziveedu Seeds Pvt. Ltd were considered as per directions from GEAC Member Secretary to the Chairman and subsequent from Chairman to Member-Secretary. There has been an order of the Hon'ble A.P. High Court also in this regard to issue orders as per law. As per law, the instructions of GEAC were abided by. The issue of an Office Memorandum in respect of the release of hybrid PCH-883 Bt2 was deferred as per law. Committee ratified the action taken by the Member-Secretary.

Remarks/Views by the Members

The Chairman informed that though the meeting was earlier scheduled for 4th week of May, 2009 it was advanced on account of the request from National Seeds Association of India (NSA) in view of the beginning of the crop season in the South. He also drew the attention of the Members on the letter received from NSL wherein the language used against one of the Standing Committee Members was highly objectionable. Members unanimously expressed their displeasure on NSL's allegations and recorded that the decision taken in the 1st meeting of the Committee was not of a single member's decision and it was based on the consensus among the Standing Committee Members. Members shared their views and suggestions on the review of applications for commercial release of Bt cotton hybrids expressing approved events under 'Event based approval mechanism (EBAM)' to make the system more efficient. The members raised the issue of non-inclusion of the statement "Since the data on agronomic evaluation, pest and disease reaction etc. were not considered by the Standing Committee while scrutinizing the applications, the release of Bt cotton hybrids based on approved event/s for commercial release in the respective state may follow the same process as that is applicable for the approval of 'truthfully labelled seed' of conventional (non-Bt) cotton seeds" in the recommendation letters issued to State Governments. Member Secretary clarified that



recommendation letters were issued as per the letter and TOR for the Standing Committee, received from the member secretary, GEAC.

Recommendations of the Bt cotton hybrids to referral laboratories

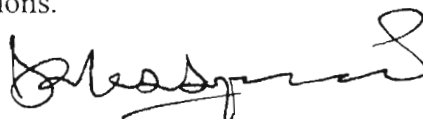
Various applications submitted by the applicants were considered by the Standing Committee taking into account the TOR of the Committee. As the sowing season is going to be over and no further meeting is proposed to be held in the near future, the applications received after 1.5.2009 were also considered as a special case. The committee also decided that in future no application received after the prescribed date will be considered by the Committee. The Standing Committee kept in view the following parameters for evaluating and deciding the commercial release of the Bt. Cotton hybrids expressing four approved events under 'event based approval mechanism (EBAM) while making recommendations for the consideration of the different State Agriculture Departments with information to GEAC:

1. Confirmation of gene/ event through molecular characterization by the licensor that the gene/s which is being used is one of the approved events;
2. Level of protein expression in green house and field trials;
3. Morphological characters using DUS descriptors;
4. Bio-efficacy data generated in laboratory conditions;
5. Authorization certificate/ No Objection Certificate (NOC) from technology provider in case of sub-licensee

Dr. Monga informed that in most of the applications for BGII cotton hybrids, bioefficacy data has been given only for *Helicoverpa armigera*. The Committee therefore recommended that protein expression data may be considered for evaluation of the applications and the minimum level of protein expression 60-90 days after sowing (DAS) for complete introgression of genes for cry 1Ac and cry 2Ab, in consultation with Dr. Kranthi and the technology provider as per the NOC documents. Based on the stipulations of GEAC, the Standing Committee recommended different hybrids in North, Central and South zones for their biosafety clearance as per Annexure-II. The committee directed the Member-Secretary to issue letters to all State Agriculture Departments on the same lines as done earlier. The Committee also recommended that the applications submitted with xerox copy of the NOC from the Technology provider, the recommendation letters should be issued only after obtaining the original NOC.

Other items with the permission of the Chair

1. In view of the submission of the technology provider and the *sub-judice* matter before PPV&FRA, the applications of M/s. Nuziveedu Seeds and M/s. Prabhat Agrotech were deferred in the 1st meeting of the Standing Committee for discussion by the GEAC. Based on the communications received from GEAC and the order from the Hon'ble High Court of Andhra Pradesh and based on the communication received from Chairman, Standing Committee, the letters to State Agriculture Departments/ Prabhat Agri Biotech Ltd./ Nuziveedu Seeds Pvt. Ltd., Hyderabad for release of Bt cotton hybrids of approved events excluding PCH- 883 Bt2 for North and Central zones were issued on 4.05.2009 & 5.05.2009 respectively. The Standing Committee ratified the recommendations.

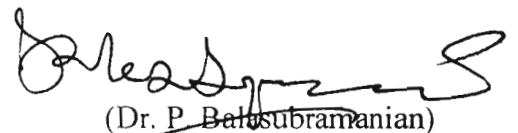


3 The members discussed on the preparation of guidelines to review applications for commercial release on Bt cotton hybrids expressing approved events under 'Event Based Approval Mechanism (EBAM)'. Members agreed that they would share their views through e-mail and the consolidated views may be examined by CICR for finalizing the draft guidelines in the next meeting for onward submission to GEAC for further consideration.

4. The committee discussed on the Notice received from the advocate of M/s. Nuziveedu Seeds Pvt. Ltd., Hyderabad to accord permission for Bt cotton hybrid PCH 883 Bt2 indicating the contempt of Court case for not releasing PCH-883. Committee noted that as per communication received from M/s. Prabhat Agri Biotech Ltd. and M/s. Nuziveedu Seeds Pvt. Ltd., Hyderabad, the germplasm of PCH-883 pertains to M/s. Nuziveedu Seeds Pvt. Ltd. licensed to M/s. Prabhat without any regulatory approval from RCGM. This is in contrary as per law and M/s. Nuziveedu may be reprimanded in this case as per the directions of GEAC. Legally there is no record with RCGM that Nuziveedu has transferred any transgenic material to M/s. Prabhat Agri Biotech. The committee noted that the issue has already been discussed by the GEAC and GEAC has already constituted an Appellate Authority for the Standing Committee with Chairman and Co-Chairman of the GEAC. Any applicant aggrieved with Standing Committee may appeal to the Appellate Authority for further consideration as per law. As regards DUS characters, the committee was of the view that the representation made by M/s. Mahyco requires natural justice and as per law only PVP&FRA can confirm about the similarities of DUS characteristics as claimed by M/s. Prabhat Agrotech and M/s. Nuziveedu and the same may be referred to PVP&FRA as regards PCH-883 Bt2 is concerned.

With the above, the meeting ended with thanks to the Chair.

The minutes approved.



(Dr. P. Balasubramanian)

Chairman, Standing Committee &
Director, CPMB, TNAU, Coimbatore

Place: Coimbatore
Date: 23.05.2009

List of Participants

1. Dr. P. Balasubramanian
Chairman, Standing Committee &
Director, CPMB, TNAU, Coimbatore
2. Dr. Dilip Monga,
Head, CICR, Sirsa.
3. Dr. N. Gopalakrishnan
Head, CICR, Coimbatore.
4. Dr. K. K. Tripathi,
Adviser, DBT
5. Mrs. Rajalakshmi Muralidharan,
Scientist D, DBT



[Handwritten signature]