

**Minutes of the 1st 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 17<sup>th</sup> April, 2009 in Room No. 727, DBT, New Delhi**

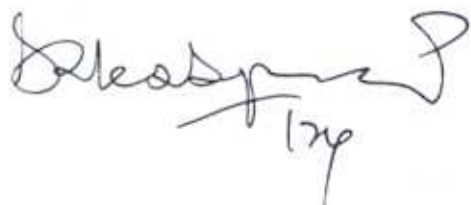
The 1st meeting of the Standing Committee to review applications for commercial release of Bt cotton hybrids expressing approved events under 'event based approval mechanism (EBAM)' was held on 17<sup>th</sup> April, 2009 in Room No.727, DBT, New Delhi under the Chairmanship of Dr. P. Balasubramanian, Director, Centre for Plant Molecular Biology (CPMB), TNAU, Coimbatore. The list of participants is enclosed at Annexure-I.

At the outset, Dr. Balasubramanian welcomed all participants and requested Member Secretary of Genetic Engineering Approval Committee to brief the participants the background of the meeting. Dr. Ranjini Warriar, Member secretary, GEAC informed that as per the approval of GEAC in its meeting held on 02.04.2008, MoE&F had constituted a Standing Committee to review applications for commercial release of Bt cotton hybrids expressing approved events under 'Event based approval mechanism (EBAM)'. She requested the Committee to devise detailed procedures and guidelines in accordance with the terms and conditions stipulated by GEAC in its OM No. 13/39/2007-CS-II dated 16.04.2009. She also requested all members/experts to share their views/comments/suggestions on the review of applications for commercial release of Bt cotton hybrids expressing approved events under 'Event based approval mechanism (EBAM)' so that these suggestions based on their merit can be incorporated in the review mechanism for making the system more effective.

Dr. K.K. Tripathi, Member Secretary, RCGM welcomed all members and informed that a total of 25 companies have submitted about 120 applications for approval for commercial release of 217 Bt cotton hybrids expressing approved events under 'Event based approval mechanism (EBAM)' in north, central and south zones. The Chairman then requested all members of the Standing Committee to share their views and suggestions. Members deliberated in detail on the Terms of Reference (TOR) of the Committee and unanimously agreed with the same.

Various applications submitted by the applicants were considered by the Sub-committee taking into account the TOR of 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:

- a) Confirmation of gene/ event through molecular characterization by the licensor that the gene/s which is being used is one of the approved events;
- b) Level of protein expression in green house and field trials;
- c) Morphological characters using DUS descriptors;
- d) Bio-efficacy data generated in laboratory conditions;
- e) Authorization certificate/ No Objection Certificate (NOC) from technology provider in case of sub-licensee; and
- f) The Standing Committee shall lay down rules and procedure for submission of application and conduct of the meetings.



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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. In view of the submission of the technology provider and the sub-judice matter of PPV&FRA, the applications of M/s. Nuziveedu Seeds and M/s. Prabhat Agrotech were deferred for discussion by the GEAC.

The application of M/s. Ajeet Seeds was rejected as the listed hybrids were not approved by MEC in 2008 i.e. ACH-155-2 while no data was submitted to MEC for ACH-177-2 as it is not listed in the records of SAU/ ICAR trials. Moreover, the NOC from the Technology provider is that of 2008 and the latest i.e. of 2009 needs to be submitted.

It was discussed that for drawing of 10% samples, the seed companies and State Agriculture Departments would send the seed samples (1 packet with 450 gms each) to the referral laboratory at CICR, Nagpur of all recommended Bt cotton hybrids of approved events from the company. The CICR, Nagpur would do the testing of 10% samples randomly selected from the samples received. Rs. 10,000/- has been fixed as the fee per every hybrid submitted which may be deposited at CICR, Nagpur by the company. The amount should be deposited by CICR, Nagpur in a separate account under a project-head 'Bt event testing' in a Nationalized bank and will maintain separate accounts. The company should also provide the event specific primer sequence details to CICR, Nagpur for scientific scrutiny and verification of the claims submitted along with the affidavit/s.

The Member-Secretary may issue letters to all State Agriculture Departments as follows:


"The applications containing affidavits of event data affirmation of the SO & SO Bt cotton hybrids of XYZ company were screened by Standing Committee for its Bt event confirmation, Bt protein expression and also for molecular as well as morphological characters. The NOC of the technology provider was also authenticated. This So & SO hybrid meets the basic requirements for commercialization as transgenic Bt cotton containing already approved/ commercialized SO & SO event and is ready for commercial release. Permission for registration and commercialization of SO & SO hybrid(s) is recommended to the states coming under north/ central/ south zone on the basis of terms & conditions laid down by the respective State Department of Agriculture as adopted for conventional (non-Bt) cotton seeds. 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 labeled seed' of conventional (non-Bt) cotton seeds."

The Committee thanked Dr. Ranjini Warriar, Member-Secretary, GEAC and Director, CS, MoE&F for providing necessary information and support.

The committee decided to meet again in the 4<sup>th</sup> week of May, 2009. The last date for submission of applications for Central and South zones for commercial release of Bt cotton hybrids containing approved events/ genes has been fixed as 1<sup>st</sup> May, 2009.

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

**The minutes approved.**

  
(Dr. P. Balasubramanian)  
Chairman, Standing Committee & Director,  
CPMB, TNAU, Coimbatore

.. Members:

1. Dr. Dilip Monga,  
Head, CICR, Sirsa.
2. Dr. N. Gopalakrishnan  
Head, CICR, Coimbatore.
3. Dr. K. R. Kranthi,  
Director, CICR, Nagpur
4. Dr. Ranjini Warriar,  
Director, MoE&F, New Delhi
5. Dr. K. K. Tripathi,  
Adviser, DBT
6. Mrs. Rajalakshmi Muralidharan,  
Scientist D, DBT

D Monga 17/4/09

N. Gopalakrishnan  
17/4/2009

K. R. Kranthi  
17-4-09

Ranjini Warriar  
17/4/09

K. K. Tripathi  
17/4/09

Rajalakshmi Muralidharan  
17-4-09

Place: New Delhi

Date: 17.04.2009

[Signature]  
17/4/09

## Annexure-I

### **List of Participants:**

1. Dr. P. Balasubramanian  
Chairman, Standing Committee &  
Director, TNAU, Coimbatore
2. Dr. Dilip Monga,  
Head, CICR, Sirsa.
3. Dr. N. Gopalakrishnan  
Head, CICR, Coimbatore.
4. Dr. K. R. Kranthi,  
Director, CICR, Nagpur
5. Dr. Ranjini Warriar,  
Director, MoE&F, New Delhi
6. Dr. K. K. Tripathi,  
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7. Mrs. Rajalakshmi Muralidharan,  
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