

Minutes of the 15th 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 in DBT, New Delhi on 03.05.2016

The 15th 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 03.05.2016 in Room No. 727, Department of Biotechnology, New Delhi under the Chairmanship of Dr. Dilip Monga, Head, CICR Regional Station, Sirsa, Haryana. The list of participants was as under:

A. Members

1. Dr. Dilip Monga, Head, CICR Regional Station, Sirsa, Haryana - Chairman
2. Prof. Ramesh Gumber, Addl. Director of Research & Head, Plant Breeding, PAU, Ludhiana
3. Shri R. K. Mishra, Director (Seeds), Department of Agriculture & Cooperation, Ministry of Agriculture, Krishi Bhavan, New Delhi
4. Dr. N. V. Naidu, Director of Research, Acharya N.G. Ranga Agricultural University (ANGRAU), Guntur, A.P.
5. Dr. D. Raji Reddy, Director of Research, Professor Jayashankar Telangana State Agricultural University (PJTSAU), Rajendranagar, Hyderabad, Telangana
6. Dr. S. R. Rao, Member Secretary, RCGM & Scientist-G, DBT
7. Dr. Rajalakshmi Muralidharan, Member Secretary, Standing Committee & Scientist-E, DBT

B. Special Invitees

1. Dr. Nitin Jain, Scientist-E, DBT
2. Dr. Amit Parikh, Scientist-D, DBT
3. Dr. V. Siva Reddy, Chief Scientific Officer, BSU, New Delhi
4. Dr. Sangeeta Agarwal, Chief (Agriculture), BSU, New Delhi
5. Dr. Govind Kumar Rai, Scientist (Agri. Biotechnology), BSU, New Delhi

Dr. A. H. Prakash, Project Coordinator, AICCIP & Head, CICR- Regional Station, Coimbatore; Dr. D. P. Waskar, Director of Research, Vasant Rao Naik Marathwada Krishi Vidhyapeeth, Parbhani, Maharashtra; and ICAR representative could not attend the meeting.

1. Welcome Remarks by the Chairman

The Chairman, Standing Committee extended a formal welcome to the members of the Standing Committee and initiated the process of the meeting.

2. Remarks/Views by the Members

The Chairman highlighted the problems being faced by cotton growers in the country and opined that the evaluation of the applications for commercial cultivation should be done carefully and judiciously. Other members also agreed to his views. Dr. S. R. Rao, Member Secretary, RCGM & Advisor, DBT made a brief presentation on "Analysis of applications for consideration by the Standing Committee under EBAM for

commercialization of Bollgard II Bt cotton hybrids incorporating stacked *cry1Ac* and *cry2Ab* genes". After deliberations, the Committee unanimously agreed that the minimum criteria on the following parameters should be strictly adhered to while scrutinizing the applications for commercial release of Bt cotton hybrids under EBAM:

- (1) Bioefficacy data: The % mortality of *Helicoverpa armigera* should be 95 ± 5 .
- (2) Protein expression:
 - a. For Cry1Ac: lower cut off level: 4.02 $\mu\text{g/g}$ dry weight (average of all measurements)
 - b. Cry2Ab: lower cut off level: 280.02 $\mu\text{g/g}$ dry weight (average of all measurements)
- (3) Yield performance: Seed cotton yield of the test hybrid should be statistically superior to the best performing BG-II check hybrid.
- (4) CLCuV disease resistance (for North Zone applications): Resistant, Moderately resistant or Moderately susceptible

He also informed that 2 new parameters viz., (1) proposed refugia strategy and an Undertaking on amount to be spent for examination/education to farmers on the use and benefits of refugia and (2) Boll damage measured by ETL at 10%, were included in the 'Call for Applications'.

3. Action taken report by the Member- Secretary

Member Secretary informed that necessary follow up action has already been taken on the recommendations of the Standing Committee in its 14th meeting held on 1-2 May, 2015 and letters were issued to State Agriculture Departments/applicants under intimation to the GEAC.

4. Recommendations of the Bt cotton hybrids to State Agri. Departments

The Committee observed that 242 applications have been received against the 'Call for Applications' for North, Central and South Zones, and the scrutiny of all applications in a single day is very difficult. The Committee therefore decided that only the applications received for North Zone will be considered in the meeting and the applications received for Central and South Zone will be considered in the next meeting.

The Committee scrutinized the applications for North Zone taking into consideration the TOR of the Committee stipulated by GEAC, the following parameters mentioned in the 'Call for Applications' published on the DBT Biosafety Website, and also based on the minimum criteria mentioned in S.No.3 above:

- (a) Confirmation of gene/ event through molecular characterization by the licensor stating that the gene/s being used is one of the approved events (LOC in original)
- (b) Level of protein expression in green house and field trials
- (c) Morphological characters using DUS descriptors as per PPVF&RA guidelines
- (d) Bio-efficacy data generated in laboratory conditions
- (e) Authorization certificate/ No Objection Certificate (NOC) in original from technology provider in case of sub-licensee
- (f) Affidavits duly signed by the Notary on Stamp Paper

- (g) Performance trial report including agronomic parameters, yield with CD & CV, pest & disease reaction for the proposed Bt cotton hybrid, fibre quality attributes, spinning potential [supported by CIRCOT (ICAR) data] etc. at least for one year, for both rainfed and irrigated situations as evidenced by at least one SAU/ ICAR-AICCIP trial from respective SAU centre from each State; Seed cotton yield should be statistically significant over best performing Bt check in respective state.
- (h) Data on tolerance of Bt cotton hybrids to CLCuV as evaluated by SAUs in North Zone/CICR, Sirsa

Based on the SAU/AICCIP-ICAR reports, the Committee recommended the Bt cotton hybrids for commercial cultivation in respective States in North Zone. The Committee directed the Member Secretary to issue the recommendation letters to different State Agriculture Departments in North Zone, for recommended Bt cotton hybrids under intimation to GEAC.

5. Representations from National Seed Association of India (NSAI) requesting to dispense away with the stipulation of submission of 'No Objection Certificate' in original from technology provider by the Seed Companies for commercialization of Bt cotton hybrids under Event Based Approval Mechanism

The Committee observed that NSAI has submitted representations addressed to (1) Hon'ble Minister of State for Environment, Forest & Climate Change dated 14.4.2016 (2) Hon'ble Minister of S&T and ES dated 29.4.2016, (3) DDG (Crops), ICAR, New Delhi dated 29.4.2016 and (4) Member Secretary, Standing Committee dated 13.4.2016 on the above subject. The Committee also noted that Member Secretary, Standing Committee has already sent a copy of the representation to Member Secretary, GEAC with a request to communicate the decision on the representation, on 26.4.2016, and the reply from GEAC is awaited. The Committee observed that since the GEAC had stipulated the condition of submission of NOC in original from technology provider, the request to dispense away with NOC does not come under the purview of the Standing Committee. NSAI may therefore approach GEAC to consider their request.

The Committee advised the member Secretary to include the following disclaimer in the recommendation letter to State Agri. Departments:

"The applicant(s) shall be responsible for obtaining other requisite approvals under applicable legislations from concerned agencies (public & private) before commercial release of recommended Bt cotton hybrid(s)".

6. Communication from Mahyco Monsanto Biotech (India) Pvt. Ltd. informing GEAC regarding the termination of Sub License Agreements of Nuziveedu Seeds Ltd., Prabhat Agri Biotech Ltd., and Pravardhan Seeds Pvt. Ltd.

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7. Communications from Nuziveedu Seeds Ltd., Prabhat Agri Biotech Ltd., and Pravardhan Seeds Pvt. Ltd. requesting to consider their applications for commercial release of Bt cotton hybrids under EBAM

The Committee noted that Nuziveedu Seeds Ltd., Prabhat Agri Biotech Ltd., and Pravardhan Seeds Pvt. Ltd. have not submitted any application for commercial release in

North Zone. The Committee therefore decided to consider the above requests in its next meeting for review of applications for Central & South Zones.

8. Communication from Director, CICR, Nagpur dated 4.2.2015 to make modifications in the recommendation letter to State Agri. Departments regarding the Bt cotton hybrids for commercial release in the state

The Committee deliberated on the modifications suggested by the Director, CICR, Nagpur in the last Para of recommendation letter to State Agriculture Departments. The Committee also discussed on the TOR of the Standing Committee as per the MoE&F's OM dated 31.3.2016 regarding the constitution of the Standing Committee which *inter-alia* states that the Standing Committee should "identify 10% of the total applications received and send the samples to the referral laboratory at CICR, Nagpur for verification of the claims submitted along with the affidavit. The Standing Committee shall also suggest to the GEAC other laboratories including in the private sector having requisite capability shall be identified for acting as referral laboratories for this purpose". Further, the TOR states that "Lay down procedure for identifying 10% of the applications for necessary verification."

The Committee suggested 2 other laboratories at ANGRAU, Guntur and PAU, Ludhiana, besides CICR, Nagpur, for acting as referral laboratories for this purpose and requested GEAC to confirm their capability.


The Committee observed that the minimum percentage of samples to be collected out of the ones that are recommended should also be fixed. The Committee suggested that a separate meeting may be held to discuss exclusively the ways and means to identify the applications for this purpose and seed samples and finalize the new procedure. Hence, the Member Secretary may issue the recommendation letters to different State Agriculture Departments in North Zone, for recommended Bt cotton hybrids under intimation to GEAC, on the same lines as in the previous meeting.

9. List of Bt cotton hybrids recommended for withdrawal from commercialization

The Committee noted the list of Bt cotton hybrids for withdrawal from marketing & commercialization, submitted by the applicants voluntarily in their applications. The Committee directed the Member Secretary to communicate the same to GEAC for consideration. The Committee also suggested that the strategy to recommend the Bt cotton hybrids for withdrawal can also be discussed and finalized during the meeting to finalize the procedure for selection of applications & sending seed samples for event testing confirmation.

With the above, the meeting ended with thanks to the Chair. The minutes are approved.

Place: New Delhi
Date: 10.05.2016


(Dr. Dilip Mongra)
Chairman, Standing Committee &
Head, CICR Regional Station, Sairs, Haryana