

## **Minutes of the 16<sup>th</sup> 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 1<sup>st</sup> & 2<sup>nd</sup> June, 2016**

The 16<sup>th</sup> 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 1<sup>st</sup> & 2<sup>nd</sup> June 2016 in 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, Director of Research, PAU, Ludhiana
3. Shri R. K. Mishra, Addl. Commissioner (Seeds), Department of Agriculture, Cooperation & Farmers Welfare, Ministry of Agriculture & Farmers Welfare, 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. D.P. Waskar, Director of Research, Vasant Rao Naik Marathwada Krishi Vidhyapeeth, Parbhani, Maharashtra
7. Dr. A.H. Prakash, Project Coordinator & All India Cotton Crop Improvement Project (AICCIP) & Head, CICR - Regional Station, Coimbatore
8. Dr. S. R. Rao, Member Secretary, RCGM & Scientist-G, DBT
9. 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

#### **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**

Dr. S. R. Rao, Member Secretary, RCGM & Advisor, DBT briefed the members about the various parameters set up for scrutinizing the applications for commercial release of Bt cotton hybrids under EBAM. Members observed that some applicants have submitted old SAU reports with yield data and boll damage details. The Committee unanimously agreed that the SAU reports of only 2015-16 or 2014-15 may be considered for evaluation

of the applications. It was also decided that in future, it should be clearly mentioned in the Call for Applications, SAU reports of recently conducted trials out of past 2 years need to be submitted along with the application.

### **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 15<sup>th</sup> meeting held on 03.05.2016 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 scrutinized 100 applications for Central Zone and 94 applications for South Zones, 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 as decided in the 15<sup>th</sup> meeting of the Standing Committee held on 3.5.2016:

- (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.

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

### **5. Representation from Kohinoor Seeds requesting to reconsider the decision of rejection of their application for commercial cultivation of Bt cotton hybrid KSCH-212 BG II in Haryana in North Zone under EBAM**

The Committee observed that Bt cotton hybrid KSCH-212 BG II of Kohinoor Seeds was not recommended for commercial cultivation in Haryana as it was susceptible to CLCuV as per the SAU trial report submitted by HAU, Hisar during 2015-16. The Committee considered the representation and opined that the SAU report clearly indicates the

susceptibility of the proposed hybrid to CLCuD in Haryana whereas the field evaluation report of CICR, Coimbatore through AICRP on cotton indicates the susceptibility of the test hybrid to CLCuD in North Zone as whole and not for a particular state. Since the application is for commercial cultivation of the test hybrid in Haryana, the SAU report from Haryana need to be considered and cannot be ignored for evaluation of the performance of the hybrid for CLCuV susceptibility.

**6. Communication from (1) 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. (2) 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 observed that the Member Secretary, Standing Committee has already sent a copy of the communication received from National Seed Association of India (NSAI), requesting to dispense with the stipulation of “No Objection Certificate (NOC)” from technology provider for approving new Bt Cotton hybrids expressing approved events under the event based approval mechanism, 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 also observed that the Seed Act, 1966 does not include transgenic seeds and therefore does not require mandatory registration. Until there is mandatory registration of transgenic seeds, GEAC has made NOC from the technology provider necessary to ensure:

- Liability, if any, in case of failure of the technology lies with the technology provider i.e. MMB and
- Only quality seeds are supplied to the farmers by the seed companies by ensuring optimum backcrossing of stability of the gene and achieving the desired level of protein expression.

The Committee deliberated on the representations received from Nuziveedu Seeds Ltd., Prabhat Agri Biotech Ltd., and Pravardhan Seeds Pvt. Ltd., and also from MMB and opined that since the GEAC had stipulated the condition of submission of NOC in original from the technology provider, the request to dispense away with NOC does not come under the purview of the Standing Committee. It was also decided that the applications submitted by Nuziveedu Seeds Ltd., Prabhat Agri Biotech Ltd., and Pravardhan Seeds Pvt. Ltd. for Central & South Zones will be evaluated by the Committee, but all recommended Bt cotton hybrids of these 3 seed companies may be communicated to the respective State Agri. Departments only after obtaining the final decision from GEAC.

**7. Discussion on the Strategy to recommend the Bt cotton hybrids for withdrawal and on the procedure for selection of 10% of the applications for sending seed samples to CICR, Nagpur for event testing confirmation**

The Chairman suggested that in order to develop the strategy for withdrawal of Bt cotton hybrids from commercial release/marketing, and selection of applications for event testing confirmation by CICR, the following details are to be examined:

- 1) Year wise list of recommended Bt cotton hybrids for commercial release by GEAC & Standing Committee from the year 2002 till date after removing the Bt hybrids which have been withdrawn by the companies voluntarily.
- 2) The list of Bt hybrids withdrawn by the companies year wise voluntarily should also be made available separately.
- 3) The number of hybrids presently available commercially in the market and their percent market share should be accessed from companies along with reasons for not bringing other hybrids which were duly approved.
- 4) The number of applications received year wise and number of applications recommended and the percentage of applications cleared by Standing Committee each year (2008 till 2016). This will give a precise picture showing the trend of percentage of applications being cleared over the years. This will also help in making the future strategies of evaluation.

Once this updated status is ready, the Standing Committee can deliberate on the issue and lay down the procedure for review of the Bt cotton hybrids approved by the Standing committee and based on the review, the Committee can recommend to the GEAC, a list of Bt cotton hybrids whose approval may be withdrawn. The Committee advised the Member Secretary to collate the above details and circulate the same to all members for further consideration.

Dr. S. R. Rao informed that the Department will organize a joint meeting in the near future, with representatives from ICAR, CICR, selected SAUs, and members of RCGM & GEAC to develop a robust mechanism and Standard Operating Procedures for evaluation of applications for commercial cultivation of Bt cotton hybrids under Event Based Approval Mechanism. This will help to remove all existing defects in the system and will redefine the minimum requirements for evaluation of the applications. He also requested all members to communicate their suggestions/comments in this regard.

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

Place: New Delhi  
Date: 10.06.2016

Sd/-  
(Dr. Dilip Monga)  
Chairman, Standing Committee &  
Head, CICR Regional Station, Sirsa, Haryana