

Minutes of the 7th 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 6th May, 2011

The 7th 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 6th May, 2011 in Department of Biotechnology, New Delhi under the Chairmanship of Dr. N. Gopalakrishnan, ADG (Commercial Crops), ICAR, New Delhi. The list of participants is enclosed at Annexure-1.

Welcome Remarks by the Chairman

Dr. N. Gopalakrishnan, Chairman, Standing Committee extended a formal welcome to all members of Standing Committee for the 7th meeting and initiated the process of the meeting.

Action taken report by the Member- Secretary

Member Secretary informed that the recommendations of the Standing Committee in its 6th meeting held on 01.04.2011 were communicated to Member Secretary, GEAC along with a copy of the minutes of the meeting on 13.04.2011 with a request to communicate the approval of GEAC on the recommendations on the applications for commercial release of Bt cotton hybrids under EBAM in North Zone. Reminders were sent on 27.04.2011 and 02.05.2011 and the reply is awaited.

Remarks/Views by the Members

Since Dr. Tripathi could not attend the 6th meeting of the Standing Committee held on 1.4.2011, Chairman, the Standing Committee made a brief account of the decisions taken in the meeting. The members discussed on the issue of Cotton leaf curl virus (CLCuV) disease problem and the importance of SAU reports in evaluating the applications for commercial release under EBAM. The members reiterated that it is the responsibility of the Standing Committee to recommend good quality hybrids which give good yield to farmers.

Recommendations of the Bt cotton hybrids to referral laboratories

The Committee deliberated on the requests and representations from the applicants for the expeditious action on the applications submitted for commercialization of Bt cotton hybrids of approved events under EBAM in view of the sowing season coming to an end in North Zone. The Committee also observed that the decision of GEAC on the recommendations of the 6th Standing Committee meeting is still awaited. In view of the fast approaching sowing season, and also the delay in the decision of GEAC on the recommendations of the Standing Committee in its 6th meeting, the Committee unanimously decided that applications for commercial release of Bt cotton hybrids categorized under Set-1; i.e. Recommended cases where SAU/ICAR data is available, yield of the hybrid is at par or better than the check (for all 3 Zones), and CLCuV disease tolerant (for North Zone hybrids only) should be recommended to respective State Agriculture Departments for commercial release. The decision on the applications which come under Set-2 (Not recommended cases: SAU/ICAR data is available, yield of the hybrid is lower than the check and is susceptible to CLCuV

disease) and Set 3 (SAU/ICAR data not submitted and the applicants may be asked to submit the same) should be taken after obtaining the communication from GEAC. The Committee requested GEAC to expedite the decision.

The Committee examined the SAU report submitted by M/s; JK Agri Genetics Ltd. Hyderabad. The Committee noted that the same was not submitted along with their original application for commercial release of Bt cotton hybrid JKCH 0109 (Mon 15985) for North Zone and therefore it was categorized under Set-3 in the meeting held on 1.4.2011. The Committee recommended Bt cotton hybrid JKCH 0109 (Mon 15985) for commercial release in North Zone along with other hybrids categorized under Set-1 as per Annexure-2

The Committee scrutinized the applications for Central and South Zones taking into consideration the Terms of Reference of the Committee stipulated by GEAC and also the additional parameters mentioned in the Call for Applications published on the DBT Biosafety Website. The Standing Committee considered the following parameters for evaluating and recommending 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 under intimation to the 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 (LOC in original).
2. Level of protein expression in green house and field trials;
3. Morphological characters of the parents and the hybrids using DUS descriptors as per PPVF&RA guidelines;
4. Bio-efficacy data generated in laboratory conditions;
5. Authorization certificate/ No Objection Certificate (NOC) from technology provider (in original) in case of sub-licensee;
6. Affidavits duly signed by the Notary on Stamp Paper.
7. One year field trial data from concerned SAU/ICAR-AICCP report on the performance of the particular hybrid
8. Data on tolerance of Bt cotton hybrids to Cotton leaf curl virus in North Zone as evaluated by SAU centre in North Zone/CICR, Sirsa.
9. The Standing Committee shall lay down rules and procedure for submission of application and conduct of the meetings.

Based on the SAU/ICAR report, the Committee recommended the Bt cotton hybrids for commercial release in Central and South Zones as per Annexures 3A, 3B, 4A & 4B. The

decision on the applications which come under Set-2 (Not recommended cases: SAU/ICAR data is available, yield of the hybrid is lower than the check) and Set 3 (SAU/ICAR data not submitted and the applicants may be asked to submit the same) were deferred till the receipt of final decision from GEAC.

The Committee directed the Member Secretary to issue recommendation letters to different State Agriculture Departments in North, Central and South Zones for recommended Bt cotton hybrids under intimation to GEAC. Para 2 & 3 of the recommendation letter was modified by the Committee as under:

“2. The applications were scrutinized by the Standing Committee as per new procedure for commercial release of Bt cotton hybrids vide Revised O.M. No. 13/39/2007-CS-II dated 17.04.2009 issued by MoE&F and as per the following:

- 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.
- f) SAU trial reports
- g) Report on CLCuV tolerance (for North Zone only)

3. Based on the above procedure, the Standing Committee has recommended the following Bt cotton hybrids for commercial release in the Zone (XYZ States) to the State Agriculture Department subject to terms & conditions and related prevalent policies laid down by the respective State Department of Agriculture as adopted for conventional (non-Bt) cotton seeds/hybrids or truthfully labeled seeds as per the State Government's procedures. It is further suggested that these hybrids may be released for commercial cultivation in respective States based upon the agronomic performance and other desirable features of the hybrids for realization of profitable and sustainable yield by the cotton farmers”.

Other items with the permission of the Chair:

- 1) Clarification received from Member Secretary, GEAC on the request received from M/s. Green Gold Seeds Ltd., Aurangabad to issue an amendment letter highlighting “Permission for commercial release of Bt cotton hybrids’ instead of “Recommendation for commercial release of Bt cotton hybrids”

The Committee noted the following clarification received from Member Secretary, GEAC:

Point 5 line 4 of the Revised OM dated 17.4.2009 on New Procedure for Commercial release of Bt cotton Hybrids expressing Approved Events clearly states that the “recommendations of the Standing Committee may be forwarded to the Secretary, State Department of Agriculture of the concerned states under intimation to GEAC”. This information may be forwarded to State Agriculture Department and Commissioner of Agriculture, M.P. along with the letter from M/s. Green Gold Seeds Ltd. For any further clarification, the State Government may write to the GEAC/Standing Committee.

The Committee directed the Member Secretary to initiate necessary follow-up action accordingly.

- 2) Requests from Sri Sathya Agri Biotech Pvt. Ltd., Hyderabad and Sri Rama Agri Genetics (I) Pvt. Ltd., Kurmool for issuing the commercial approval of Bt cotton hybrids for Central and South Zones as the deadline for submission of applications for commercial release of Bt cotton hybrids in Maharashtra as per the instructions from State Agricultural Commissioner, Maharashtra was 5th May, 2011.

The Committee considered the requests and opined that the meeting of the Committee was scheduled on 6th May only. The Committee examined their applications and made specific recommendations. The Member Secretary was directed to communicate the same.

- 3) The Committee observed that many applicants are submitting the same morphological characteristics for different hybrids. There should be some mechanism to identify different hybrids based on DUS characteristics and these morphological variations should be submitted along with the application. The Committee requested GEAC to look into the matter.

With the above, the meeting ended with thanks to the Chair. The minutes approved with incorporation of suggestions and modifications.

Sd/-
(Dr. N. Gopalakrishnan)
Chairman, Standing Committee &
ADG (Commercial Crops), ICAR, New Delhi

Place: New Delhi
Date: 08.05.2011