

**F. No. 13/39/2007-CS-II**  
**Ministry of Environment and Forests**  
**Government of India**  
**CS Division**  
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**REVISED OFFICE MEMORANDUM**

**New Procedure for Commercial Release of Bt Cotton Hybrids Expressing  
Approved Events**

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The Ministry of Environment and Forests, Government of India, New Delhi under the 'Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989 (the Rules, 1989)' notified under the Environment (Protection) Act, 1986, is concerned with the environmental release of genetically modified organisms and products thereof in the territory of India.

The Genetic Engineering Approval Committee (GEAC) established under Rule 4 of 'the Rules, 1989' has adopted 'event based approval mechanism (EBAM) in respect of Bt cotton hybrids expressing approved events in its meeting held on 2.4.2008 and subsequently a new procedure under the EBAM was adopted by the GEAC in its meeting held on 14.1.2009. In accordance with the decision taken therein, the following new procedure shall be made applicable in respect of Bt cotton hybrids expressing approved events. Other details pertaining to the above subject-matter are given as under:

- 1. Scope and Application:** The 'event based approval mechanism' shall be applicable for Bt cotton hybrids expressing four events namely; *cry 1Ac* (MON 531 event), *cry 1 Ac* and *cry 2 Ab* (MON 15985 Event), (*cry 1 Ab + cry Ac*) GFM' and *cry 1 Ac* (Event 1). The new procedure shall be applicable only after the event completes three seasons of commercial cultivation.
- 2. Composition of the Standing Committee:** In accordance with the decision taken by the GEAC, a 'Standing Committee' will be constituted by the Ministry of Environment and Forests and serviced by the Department of Biotechnology, Ministry of Science and Technology with the following composition:

S.No.	Name and Designation of Experts	Designation in the Standing Committee
1.	Dr. P. Balasubramanian, Director, Centre for Plant Molecular Biology, TNAU, Coimbatore.	Chairman
2.	Dr. D. Monga, Head, Regional Station, Central Institute of Cotton Research, Sirsa, Haryana.	Member
3.	Dr. K. R. Kranthi, Principal Scientist, CICR, Nagpur	Member
4.	Dr. N. Gopalakrishnan, Project Coordinator, All India	Member

	Cotton Crop Improvement Project (AICCIP) or his nominee.	
5.	<i>Dr. K. K. Tripathi, Adviser, DBT and Member Secretary, RCGM</i>	<i>Member</i>
6.	<i>Mrs. Rajalakshmi Muralidharan, Scientist D, DBT and Co-Member Secretary, RCGM</i>	<i>Member Secretary</i>

**3. Terms of Reference (TOR):** The 'Standing Committee' shall:

- a. Evaluate the duly submitted applications for commercial release of Bt cotton hybrids expressing approved events and verify that the affidavit/s is/are in proper order;
- b. Identify 10% of the total applications received and send the samples to the referral laboratory at CICR, Nagpur, for scientific scrutiny and verification of the claims submitted along with the affidavit/s. The Standing Committee shall identify laboratory/laboratories in public/ private sector having requisite capability for referral and to suggest it/them forthwith to the GEAC;
- c. Recommend the hybrid for commercial release in the given State subject to the condition that punitive action may be initiated in case of providing any wrong information/ declaration irrespective of whether or not the application falls under the 10% category.
- d. Act as office of record and shall maintain all the particulars of the records of the applications submitted to it; and
- e. Lay down a detailed set of procedures for identifying 10% of the applications for necessary verification.

**4. Submission of Application:** The applicants (private/public sector organizations) desirous of commercial cultivation of Bt cotton hybrids expressing approved events shall file their applications along with affidavits to the 'Standing Committee' confirming/stating 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; and
- f. The Standing Committee shall lay down rules and procedure for submission of application and conduct of the meetings.

**5. Process Applicable after the Application Passed the Test of Scrutiny:** Once the application has cleared the scrutiny of the Standing Committee, the release of Bt cotton hybrids for commercial release in the respective state may follow the same process as that is applicable for conventional cotton (non Bt) seeds. Accordingly, the recommendations of the 'Standing Committee' shall be forwarded to the Secretary, State Department of Agriculture of the concerned states under intimation to the GEAC.

**6. Tenure:** The tenure of the 'Standing Committee' shall be for a period of three years from the date of notification the 'Standing Committee' or till such substitute is issued by the Ministry of Environment and Forests, Government of India, whichever is earlier.

**7. Miscellaneous:** The 'Standing Committee' shall be serviced through the Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi.

**8. Date of Application:** The new set of procedure shall be made applicable with immediate effect.

**9. Punitive Measures/ Penalty:** The applicant shall be liable for any wrong statement/ declaration provided in the affidavit submitted. Appropriate punitive measures shall be taken against such errant applicants under the Environment (Protection) Act, 1986.

**10.** The applications for commercial release of Bt cotton hybrids expressing approved events shall be submitted to: Mrs. Rajalakshmi Muralidharan, Scientist D, DBT and Member Secretary, Standing Committee, Department of Biotechnology, Block No. 2, Room No. 809, 8<sup>th</sup> floor, CGO Complex, Lodi Road, New Delhi-110 003 (Tel:24363029; E-Mail: [m.rajalakshmi@nic.in](mailto:m.rajalakshmi@nic.in))

This is issued with the approval of the Competent Authority in the Ministry of Environment of Forests

  
17/04/09  
(A.K Goyal)  
Joint Secretary

**Dated: 17.4.2009**