

**STANDARD OPERATING PROCEDURES (SOPS) FOR CROSS-BRED
GENETICALLY MODIFIED (GM) VARIETY**

Step 1:

- a) The applications for crossbreeding will be submitted to TAC through the notified IBC of the concerned institute/organization as per Pakistan Biosafety Guidelines, 2005 (amended 2024).
- b) The applicant shall have to submit a copy of the agreement/authorization made with the technology developer, in case, the applicant is not the technology developer of the GM technology for which biosafety clearance has been issued by the National Biosafety Committee (NBC).
- c) Prior to agreement, the technology developer/license holder shall submit an application as mentioned in 1(b), intimating Chairperson NBC as per Rule 11 of Pakistan Biosafety Rules, 2005 (amended 2024).

Step 2:

The authenticity of the cross-bred line shall be ensured by parties, the technology developer and agreement holder in intimation with Pak-EPA from at least 01 of the following designated public sector laboratories;

- i) National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad.
- ii) National Centre of Excellence in Molecular Biology (CEMB), Lahore.
- iii) Agriculture Biotechnology Research Institute (ABRI), Ayub Agriculture Research Institute (AARI), Faisalabad.
- iv) National Institute for Genomics and Advanced Biotechnology (NIGAB), Islamabad.
- v) Any other certified laboratory.

Note: *These four (04) laboratories have been integral part of National Agricultural Research System (NARS) of Pakistan for testing/evaluation GM Plants since 2009. The laboratories are well equipped with highly trained manpower and state of art infrastructure including highly advanced equipment brands (BioRed^R, Beckman Coulter^R, P, BioTek^R, Applied Biosystems^R, etc.).*


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Step 3:

Confined field trials (CFT) for risk assessment shall be conducted as per Chapter 11 of the Pakistan Biosafety Guidelines, 2005 (amended 2024), however, those cross-bred lines shall be exempted from CFT, if risk assessments/biosafety studies of the parentage/GMO lines have already been established with NBC.

Step 4:

The GM lines developed through crossbreeding shall undergo a two-year evaluation in the National Coordinated Varietal Trial (NCVT) to assess agronomic traits, gene expression, along with a Distinctness, Uniformity, and Stability (DUS) test only after the approval granted by NBC.

Step 5:

Based on successful NCVT results, the applicant shall apply for a commercialization license to TAC/NBC.

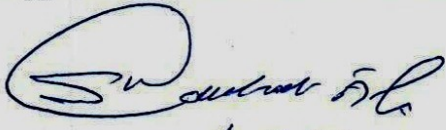
Step 6:

After receiving recommendations from the Variety Evaluation Committee (VEC) and subsequent approval from the Provincial Seed Council (PSC), the variety shall be released for commercial cultivation.

Transitional Provision

Cases of varieties at the final stage prior to the implementation of the above SOPs (step 1 to step 6) shall be submitted to respective IBC(s) within 90 days after the publication of advertisement of SOPs. Provided that, after implementation of the SOPs, new cases of GM variety development through cross breeding shall be processed accordingly (step 1 to step 6).

These SOPs ensure compliance with Pakistan Biosafety, Rules 2005(amended 2024) and National Biosafety Guidelines, 2005 (amended 2024) while facilitating the development and approval of cross-bred GM varieties.


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