

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

Step 1:

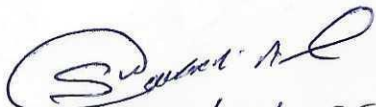
- a) The applications for crossbreeding will be submitted to Biosafety Clearing House (BCH)/TAC through notified IBC of the concerned institute/organization.
- b) The applicant shall have to submit a copy of the agreement/authorization made with the technology developer, in case, the applicant is not 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) and intimate to the Chairperson NBC through BCH/TAC as per Rule-11 of Pakistan Biosafety Rules-2005 (amended-2024).

Step 2:

The authenticity of the cross-bred line will be ensured by parties, the technology developer and agreement holder in collaboration with BCH of the 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 GMs Plant since 2009. The laboratories are well equipped with highly trained manpower and state of art*


07/03/2025


2025

infrastructure including highly advanced equipment brands (BioRed^R, Beckman Coulter^R, P, BioTek^R, Applied Biosystems^R, etc.).

Step 3:

Confined field trials (CFT) and risk assessment will 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.

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 will apply for a commercialization license to BCH/TAC/NBC.


Step 6:

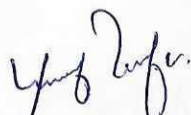
After receiving recommendations from the Variety Evaluation Committee (VEC) and subsequent approval from the Provincial Seed Council, the variety will be released for commercial cultivation.

Transitional Provision

Cases of varieties at final stage prior to the implementation of the above SOPs (1to6) may be submitted to respective IBC(s) within the prescribed period of time defined by TAC/NBC. However, after implementation of the SOPs new cases of GM variety development through cross breeding will be processed accordingly.

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


07/03/2025


07/03/2025