

STANDARD OPERATION PROCEDURE (SOP)

FOR COTTON SEED VARIETY HAVING SINGLE KNOWN EVENT & KNOWN GENE (MON 531 & Cry1Ac)

Step-1

The applicant will submit its case of known event and known gene (MON531 & Cry1Ac) to the concerned duly notified Institutional Biosafety Committee (IBC) for review. After careful review, IBC will recommend the case for the commercialization of the variety to the National Biosafety Centre (NBC) Pak-EPA, Islamabad.

Step-2

The authenticity of the seed having known event and known gene (MON531 & Cry1Ac) (type and level) will be ensured by the developer and get verified it from at least two 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.

Note: *These four (04) laboratories have been integral part of national cotton system of Pakistan for testing/evaluation of Bt. cotton 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.).*

Step-3

The proponent will submit its case for commercialization of the variety to the National Biosafety Centre (NBC), Pak-EPA, Islamabad on the prescribed application format for commercialization given in the National Biosafety Guidelines, 2005 alongwith following mandatory documents / requirement;

- i) Institutional Biosafety Committee (IBC) Assessment / Recommendation.
- ii) National Biosafety Centre, Pak-EPA process charges.
- iii) Limited available field data of the variety.
- iv) Test results (DNA & Proteins) for the type and level of toxin available in the emerging seedlings (30 to 45 days DAP) from at least two of the designated public sector laboratories.

Step-4

The National Biosafety Centre (NBC), Pak-EPA will review the case and Director General, Pak-EPA may be authorized to issue or otherwise biosafety license within maximum of 10 working days after submission of application complete in all respect.

Step-5

The license issued shall be valid for a period of two years.

Note: *These SOPs are valid exclusively for MON531 event of cotton. Other known genetic events may be reviewed by NBC on case to case basis.*