

STANDARD OPERATING PROCEDURE (SOP)
FOR
COMPLIANCE MANAGEMENT OF CURRENT SEASON
FIELD TRIALS OF GENETICALLY ENGINEERED (GE)
COTTON (*Gossypium hirsutum*) IN BANGLADESH

OBJECTIVE/PURPOSE

To Ensure Compliance with Requirements for Current Season Field Trials Management of GE cotton as Per the Regulations Governing Confined Field Trials of GEP Material in Bangladesh. Any party seeking exception from any part of this SOP shall seek approval from NCB at the time of application for a confined field trial.

CORRESPONDENCE OR ENQUIRIES

Chairperson
National Committee on Biosafety
Ministry of Environment, Forest and Climate Change
Govt. of the People's Republic of Bangladesh
Bangladesh Secretariat
Dhaka

SOP: NCB/GMP/No. 3(cotton)

COMPLIANCE MANAGEMENT OF CURRENT SEASON FIELD TRIALS OF GENETICALLY ENGINEERED (GE) COTTON (*Gossypium hirsutum*) IN BANGLADESH

1. DESCRIPTION OF THE ACTIVITY

The management of current season field trials of GE cotton in Bangladesh to ensure compliance with NCB requirements and the Guidelines governing confined field trials of genetically engineered plant (GEP) material in Bangladesh.

2. SOP AUTHORIZATION

NCB Authority:

Title:

Signature and Stamp:

Date:

Implementation Date:

In Effect Until:

3. DEFINITIONS

- 3.1. Accidental release: Any unauthorized release of a GEP material in the environment; the human food and/or livestock feed chains.
- 3.2. Anthesis: The time of flowering or pollination. Anthesis is complete when flowering or pollination is complete.
- 3.3. Authorized Party: The addressee on the notification of authorization who shall accept full responsibility for compliance with all terms and conditions of authorization.
- 3.4. Field trial: The planting of one or more GE plants in a single experiment. The field trial shall be no more than 1 Ha.
- 3.5. Genetically Engineered (GE) Cotton: Also referred to as transgenic cotton. For the purpose of this SOP, it shall be cotton research material derived through recombinant-DNA techniques.

- 3.6. Genetically Engineered Plant (GEP) Material: Also referred to as transgenic plant material; for the purpose of this SOP, shall be experimental research material derived through recombinant-DNA techniques, which has not received approval for commercial cultivation or use in food or livestock feed.
- 3.7. National Committee on Biosafety (NCB): Regulatory authority in-charged with the responsibility of regulating importation and environmental introduction of any GMO for confined trial and commercial release in Bangladesh.
- 3.8. Permanent markers or Landmarks: Physical signs or markers used to identify or designate boundaries of a Confined Field Trial (e.g. telephone poles, fences, alleys, roads or steel poles).
- 3.9. Principal Investigator (PI): The person designated by the Authorized Party as responsible for the entire research activities associated with the cotton confined field trial/trials.
- 3.10. Co-investigator: The person designated by the Authorized Party as responsible for assisting the PI entire research activities associated with the cotton confined field trial/trials.
- 3.11. Prohibited Plants: These include all volunteers of the same species as planted in the confined field trial, and sexually compatible related plant species.
- 3.12. Trial site location: The geographic location of a trial site as identified by an address, legal land location, or GPS coordinates where applicable.
- 3.13. Reproductive Isolation: Means used to prevent movement or dissemination of genetic plant material by mainly pollen or seed from the confined trial.
- 3.14. Sexually Compatible: Ability of the GEP material to cross-pollinate with other cultivated plants of the same species, or with wild plants of species related to the GEP material, and form viable hybrids without human intervention.
- 3.15. Trial Manager: The person identified to NCB by the PI or Authorized Party as responsible for ensuring the implementation of this SOP.
- 3.16. Trial site: The area where one or more field trials may be planted and that is confined by one continuous method of reproductive isolation.
- 3.17. Volunteers: Plants of the same species as the genetically engineered plant material that germinate and grow in the trial site and/or isolation distance.

4. GENERAL REQUIREMENTS

4.1. The Authorized Party and all other agents acting on behalf of the Authorized Party shall comply with this SOP.

5. REQUIREMENTS FOR PLANTING OF COTTON FIELD TRIALS

5.1. The Authorized Party shall notify NCB by written and telephone of the planting date before planting.

5.2. All equipment used to plant GE cotton shall be free of plant material before entering the trial site, including seed and vegetative material that may be present from prior operations.

5.3. All equipment used to plant GE cotton or equipment that is used in the maintenance of the trial site shall be cleaned at the trial site to eliminate unintended transport of GEP material from the trial site. Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water.

5.4. Any residual plant material recovered during the process of cleaning field equipment shall be destroyed by dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labeled herbicides and/or chemicals and disposed of on the trial site.

5.5. A map of the trial site shall be prepared by the Trial Manager and appended to the Record of Planting. Instructions for the preparation of maps are provided in Annex 1.

5.6. A Record of Planting shall be completed for each field trial site. A copy of the Record of Planting, with the appended map, shall be submitted both to NCB and to the Authorized Party within five (5) working days following the completion of planting. The original Record of Planting shall be retained by the Trial Manager in the Compliance Document Binder.

6. PERFORMANCE REQUIREMENTS FOR FIELD TRIALS OF GENETICALLY ENGINEERED COTTON

- 6.1. All four corners of each trial site shall be clearly marked with permanent markers (e.g. fence post, PVC piping) suitable to permit identification of the trial site during both the growing season and the NCB mandated period of post-harvest land use restriction.
- 6.2. All field trial sites of GE cotton shall be reproductively isolated from any sexually compatible species, sub-species or varieties that are not part of the trial by the methods described in sections 6.4 and 6.5.
- 6.3. A single field trial site shall be reproductively isolated in its entirety by no less than one continuous method of reproductive isolation.
- 6.4. Spatial isolation of field trial sites of GE cotton.
 - 6.4.1. Trial sites of GE cotton shall be spatially isolated from other cotton by a minimum isolation distance of 70 m. The spatial isolation distance shall be continuous and completely enclose the confined trial.
 - 6.4.2. The Trial Manager shall ensure that the trial site and surrounding isolation distance shall be kept free of all sexually compatible plants, including volunteers, by implementing a program of regular monitoring and rouging (see section 7).
 - 6.4.3. Any sexually compatible plants in the isolation distance shall be removed before anthesis.
 - 6.4.4. If any sexually compatible plants within the isolation distance are permitted to complete anthesis, a breach of reproductive isolation will have occurred.
 - 6.4.5. Any sexually compatible plants removed from the isolation distance shall be destroyed by dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labeled herbicides and/or chemicals and disposed of on the trial site.

7. MONITORING OF THE FIELD TRIAL BY THE TRIAL MANAGER

- 7.1. The Trial Manager, or a person so designated for this purpose by the Trial Manager, shall inspect the trial site no less than once every two weeks from the time of planting until the time of harvest.
- 7.2. The Record of Spatial Isolation shall be used to document all monitoring activities needed to ensure spatial reproductive isolation of the trial site.
- 7.3. The growth stage of any prohibited cotton shall be recorded at the time of inspection based on the Cotton Growth Stage Key (see Annex 2).

8. INSPECTION OF THE TRIAL SITE BY NCB OFFICIALS

- 8.1. Access to the trial site for the purpose of inspection shall be provided to NCB regulatory officials upon request provided they present official identification.

9. OCCURRENCE OF NON-COMPLIANCE

- 9.1. The Trial Manager and/or the Authorized Party shall orally notify NCB immediately and in writing within 24 hours of any situation where reproductive isolation of the trial site has been breached.
- 9.2. NCB shall determine the subsequent course of action.

10. CORRECTIVE ACTION IN THE EVENT OF AN ACCIDENTAL RELEASE

- 10.1. In the event of a confirmed accidental release of GE cotton all attempts shall be made to recover as much of the GEP material as possible. This material shall be destroyed.
- 10.2. If an accidental release affects an area outside the perimeter of the trial site, that location shall be marked, monitored and shall be treated in the same manner as the trial site with respect to ensuring that no additional release of material occurs. The period of monitoring will be determined in consultation with NCB.

10.3. In the event of a suspected accidental release at any location, the Trial Manager and/or the Authorized Party shall immediately notify NCB by telephone, and confirm this in writing within 24 hours.

10.4. The accidental release of GE cotton shall be immediately documented in a Record of Corrective Action. The Trial Manager shall retain the original Record, and copies shall be immediately submitted by electronics communication to NCB and the Authorized Party.

11. RECORD KEEPING

11.1. The Record of Planting and map for each trial site shall be retained by the Trial Manager in the Compliance Document Binder and one copy shall be submitted to each of NCB and the Authorized Party within five (5) working days of planting.

11.2. The Record of Spatial Isolation for each trial site shall be retained by the Trial Manager in the Compliance Document Binder.

11.3. The Compliance Document Binder shall be available for inspection by NCB regulatory officials upon request.

12. RELATED SOPS

12.1. The following SOPs shall also be consulted:

12.1.1. SOP-NCB/GMP/NO1: Transport of Genetically Engineered Plant (GEP) Material

12.1.2. SOP-NCB/GMP/NO2: Storage of Genetically Engineered Plant Material in Bangladesh.

12.1.3. SOP-NCB/GMP/NO.4: Termination/Harvest and Disposition of Field Trials of Genetically Engineered Plants in Bangladesh.

12.1.4. SOP-NCB/GMP/NO.5 cotton: Post-Harvest Management of Field Trial Sites of Genetically Engineered Cotton (*Gossypium hirsutum*) in Bangladesh

12.1.5. SOP-NCB/GMP/NO.6: The Compliance Document Binder.

13. REVIEW AND DISTRIBUTION

- 13.1. This SOP shall be reviewed by NCB no less than annually.
- 13.2. Upon revision, the revised SOP will be distributed to each Authorized Party, who shall then replace any older copies in their possession and provide copies of the revised SOP to all agents working on their behalf.
- 13.3. Archival copies of this SOP shall be maintained by Authorized Party for no less than five years.

14. ASSURANCE

- 14.1. I have read this document and understand its contents. I commit to implement the requirements under this SOP. I certify that this document will be made available to all personnel to which it applies for the purpose of implementation for full compliance.

AUTHORIZED PARTY:

NAME: _____

DESIGNATION: EXECUTIVE DIRECTOR,

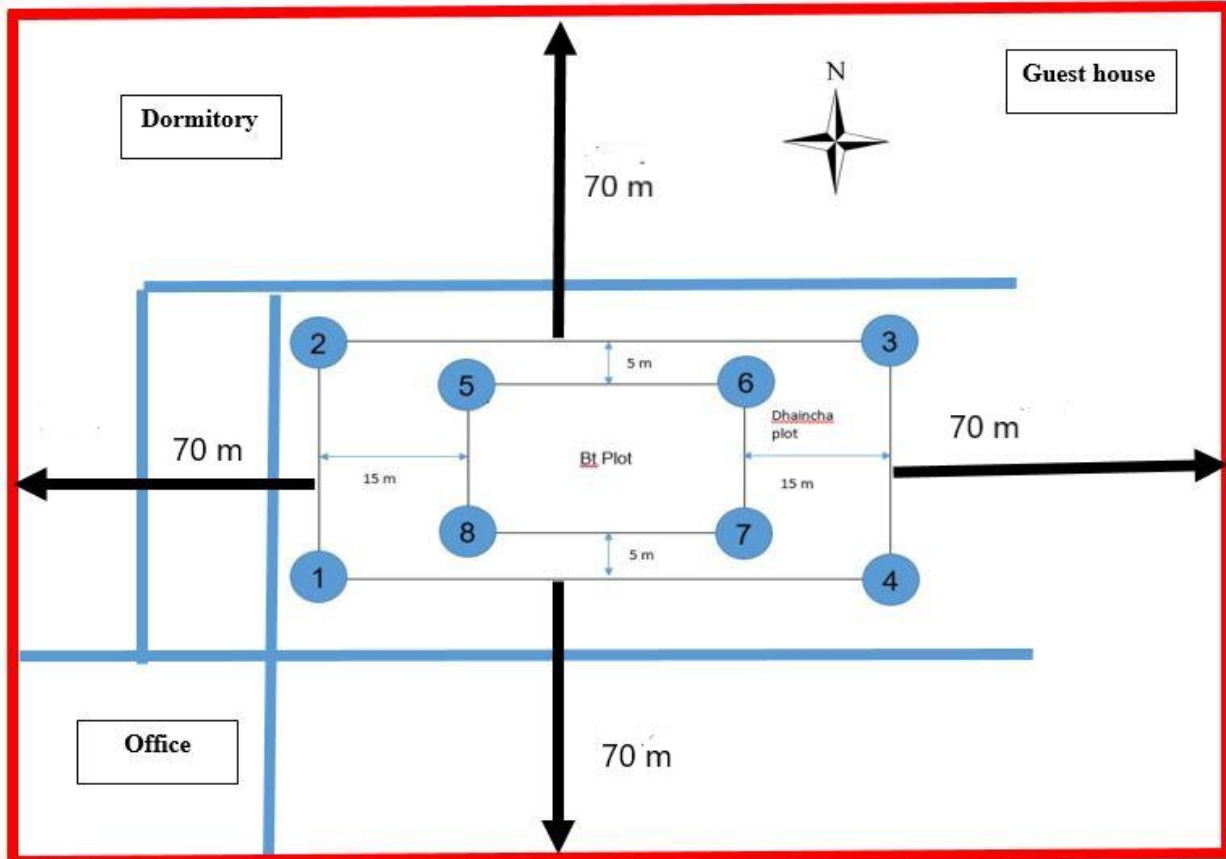
ORGANIZATION: COTTON DEVELOPMENT BOARD

SIGN: _____ DATE: _____

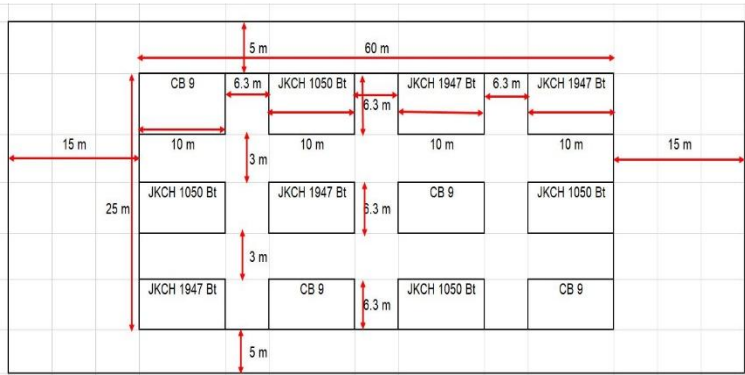
ANNEX 1: INSTRUCTIONS FOR PREPARATION OF FIELD TRIAL MAPS

1. A map of the trial site shall be prepared by the Trial Manager and appended to the Record of Planting, which must be submitted to NCB within five (5) working days of the date of planting.
2. Maps must provide sufficient detail to allow NCB-appointed monitoring officers to locate each field trial during the current and post-harvest seasons.
3. Maps must be drawn to scale and provide details on the layout of the site and distances between the field trial and surrounding features.
4. The dimensions of trial site and distances to permanent markers must be accurately reported.
5. The following items shall be included on each map of a field trial site:
 - a. Trial Manager's name, date, and signature.
 - b. A reference code for a trial site or trial(s) within a trial site, if applicable.
 - c. NCB Authorization Permit number.
 - d. Legal or descriptive land location.
 - e. GPS coordinates, (if applicable). The use of GPS locator numbers for each corner of the trial site is required to provide the most accurate information to enable verification of the trial location. All GPS co-ordinates must be obtained using units with accuracy of at least plus or minus 5 meters.
 - f. Exact trial site dimensions.
 - g. Total area planted with the GEP material, including guard rows (acres or square meters).
 - h. Distances to permanent markers or surrounding landmarks such as telephone poles, fences, alleys, roads or steel poles that can be located by a metal detector.
 - i. Label all fields within the isolation distance by the common name of the crop.
 - j. Indicate closest fields of same species as the GEP material up to 70 m from the trial site, where reasonable.
 - k. Include any natural ecosystems within a 70 m radius of the trial site(natural habitats, waterways, forests, and woodlots, hedgerows), where reasonable.
 - l. Planting date.
 - m. Compass directions, with North at the top of the page.

Example of a properly prepared trial site map for a single confined field trial of cotton.



- 1, 2, 3, 4: Boundary (GPS coordinates) of gross research plot with natural barrier
- 5, 6, 7, 8: Boundary (GPS coordinates) of Bt cotton confined field trial



Large scale view of trial areas

ANNEX 2: COTTON GROWTH STAGES

a. Cotton seed

A mature cotton seed contains all of the organs necessary to produce a small seedling. The seed is pointed on one end (the micropyle) and rounded on the other (the chalaza).

b. Germination and Seedling Development

Germination begins as the seed absorbs water and oxygen through its chalaza after planting. A week or so after seedling establishment, the first true leaf appears above the cotyledons.

c. Vegetative Growth

Cotton has an indeterminate growth habit. The first vegetative structures that appear on the main stem are main stem leaves. The branches on a cotton plant can be classified as either vegetative branches (monopodia) or fruiting branches (sympodia).

d. Fruiting

About two months after planting, flower buds called squares appear on the cotton plants. Once the cotton begins to bloom, it is said to be “flowering”. Approximately 5 to 7 days after a flower appears it usually dries and falls from the plant exposing the developing boll. Under optimum conditions it requires approximately 50days for a boll to “open” after pollination occurs.

e. Seed cotton harvesting, drying and storing

Cotton bolls are harvested in two or three times and harvested bolls are dried in the sun before storage.