STANDARD OPERATING PROCEDURE (SOP) FOR POST-HARVEST MANAGEMENT OF FIELD TRIAL SITES OF GENETICALLY ENGINEERED (GE) COTTON (*Gossypium hirsutum*) IN BANGLADESH

OBJECTIVE/PURPOSE

To ensure compliance with requirements for post-harvest Management of GE cotton field trial sites 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 the 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.5 (cotton)

POST-HARVEST MANAGEMENT OF FIELD TRIAL SITES OFGENETICALLY ENGINEERED COTTON (*Gossypium hirsutum*) IN BANGLADESH.

1. DESCRIPTION OF THE ACTIVITY

The appropriate post-harvest management of field trial sites of genetically engineered cotton (*Gossypium hirsutum*) plant material in Bangladesh.

2. SOP AUTHORIZATION

NCB Authority:

Title:

Signature and Stamp:

Date:

Implementation Date:

3. DEFINITIONS

3.1. Accidental release: Any unauthorized release of 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. NCB: Regulatory authority in charged with the responsibility of regulating importation and environmental introduction of any GMO for confined trial and commercial release.

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 (CI): The person designated by the Authorized Party as responsible for assisting the PI to the 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 POST-HARVEST MANAGEMENT OF GECOTTON FIELD TRIAL SITES

5.1. Trial sites of genetically engineered (GE) cotton shall be subject to a period of post-harvest land use restriction of 90 days.

5.2. The post-harvest period begins immediately upon harvest of the trial site or termination of the trial site for any other reason.

5.3. During the post-harvest period, no GE cotton material from trial site shall enter into the human food or animal feed chains.

5.4. The Authorized Party shall ensure that the Trial Manager maintains control of the trial site during the post-harvest period. This assurance shall be obtained in writing before the trial site is planted.

5.5. Where the trial site will not be used for subsequent cultivation of GE cotton under confined conditions, the Trial Manager shall ensure that no other cotton is cultivated on the trial site during the post-harvest period. This prohibition also applies to the isolation distance if it was included for postharvest monitoring (see 5.9.1).

5.6. The Trial Manager shall ensure that the trial site is inspected for the presence of cotton volunteers no less than ONCE EVERY FOUR WEEKS during the period that post-harvest land use restrictions are in effect.

5.7. During the post-harvest period, all cotton volunteers shall be eliminated from the trial site before anthesis and 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 in a burial pit.

5.8. If any prohibited plants are permitted to complete anthesis, a breach of reproductive isolation will have occurred and the period of post-harvest restriction shall be EXTENDED FOR ANOTHER 90 DAYS.

5.9. Only the trial site shall be subject to land use restrictions during the postharvest period with the exceptions where spatial isolation was used during the trial period (see SOP NCB/GMP/NO.3cotton) and a breach of reproductive isolation was deemed to have occurred, the trial site area plus the 70 m isolation distance shall be subject to post-harvest restrictions.

5.10. All post-harvest inspections and related activities shall be recorded in the Record of Post-Harvest Inspection.

6. MONITORING OF THE POST-HARVEST TRIAL SITE BY THE TRIALMANAGER

6.1. The Trial Manager, or a person so designated as an inspector by the Trial Manager, shall inspect the field trial site no less than ONCE EVERY FOURWEEKS for the period of post-harvest land use restriction.

6.2. At the time of inspection the growth stage of any prohibited plants of *Gossypium hirsutum* shall be recorded based on the Cotton Growth Stage Key (see Annex 1).

7. INSPECTION OF THE TRIAL SITE BY NCB OFFICIALS

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

8. OCCURRENCE OF NON-COMPLIANCE

8.1. The Trial Manager and/or the Authorized Party shall orally notify NCB immediately and in writing within 24 hours of any occurrence of non-compliance during the post- harvest restriction period.

8.2. NCB shall determine the subsequent course of action.

9. CORRECTIVE ACTION IN THE EVENT OF AN ACCIDENTAL RELEASE

9.1. 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.

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

9.3. 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 email to NCB and the Authorized Party.

10. RECORD KEEPING

10.1. The Trial Manager shall complete the Record of Post-Harvest Inspection, during the post-harvest land use restriction period. The original shall be retained by the Trial Manager in the Compliance Document Binder and, upon completion; a copy shall be submitted to the Authorized Party and to NCB.

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

11. RELATED SOPS

11.1. The following SOPs shall also be consulted:

11.1.1. SOP- NCB/GMP/NO.3 (cotton): Compliance Management of Current Season Field Trials of Genetically Engineered Cotton (*Gossypium hirsutum*) in Bangladesh.

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

12. REVIEW AND DISTRIBUTION

12.1. This SOP shall be reviewed by NCB no less than annually.

12.2. 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.

12.3. Archival copies of this SOP shall be maintained by Authorized Party for no less than five years.

13. ASSURANCE

13.1. 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 _____

SIGNATURE:_____DATE:_____

Official seal

ANNEX 1: COTTON GROWTH STAGES

Two types of cotton are commercially grown in Bangladesh e.g. American Upland Cotton (*Gossypium hirsutum*) and Hill Cotton (*Gossypium arboreum*). In addition to that *G. herbaceum* is also found in the homestead areas of Bangladesh. *G. hirsutum* is a tetraploid cotton with 2n = 52 chromosomes. G. arboreum and G. herbaceum are diploid cotton with 2n = 26 chromosomes. The GE cotton is the American Upland Cotton (*Gossypium hirsutum*).

Cotton (*Gossypium hirsutum*)is an annual crop. It completes its life cycle, from seed to seed, in one season. Cotton is usually grown for several months, although it can be cropped for over one season when growing conditions (water, fertilization, etc.) are optimal and plants are not exhausted by diseases or insect pests.

The growth stages of cotton are:

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 50 days 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.