

**STANDARD OPERATING PROCEDURE
FOR
STORAGE OF GENETICALLY ENGINEERED PLANT
(GEP) MATERIAL WITHIN BANGLADESH**

OBJECTIVE/PURPOSE

To Ensure Compliance with Requirements for Storage of GEP material 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.

CORRESPONDENCE OR ENQUIRIES

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

SOP-NCB-MOEF/GMP/NO.2

STORAGE OF EXPERIMENTAL GENETICALLY ENGINEERED PLANT (GEP) MATERIAL IN BANGLADESH

1. DESCRIPTION OF THE ACTIVITY

The appropriate storage of GEP material in Bangladesh.

2. SCOPE

This SOP will cover GEP material stored at secured containment facilities or facilities within the trial site. The storage period will include the time of receipt and entire period of the trial.

3. SOP AUTHORIZATION

NCB Authority:

Title:

Signature and Stamp:

Date:

Implementation Date:

In Effect Until:

4. DEFINITIONS

- 4.1. **Accidental release:** Any unauthorized release of a GEP material in the environment; the human food and/or livestock feed chains.
- 4.2. **Authorized Party:** The addressee on the notification of authorization who shall accept full responsibility for compliance with all terms and conditions of authorization.
- 4.3. **Devitalized:** Non viable or non-reproductive plant materials. De-vitalization can be achieved through autoclaving or chemical treatment.
- 4.4. **Facility Manager:** Person designated as responsible for the storage (before or at planting, during planting and after harvest) of the GEP material by the Authorized Party or Principal Investigator.
- 4.5. **Genetically Engineered:** Organisms modified by recombinant-DNA techniques.
- 4.6. **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.
- 4.7. **NCB:** Regulatory authority charged with the responsibility of regulating importation and environmental introduction of any GMO for confined and field release.
- 4.8. **Plant material:** Propagatable material (e.g. seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagatable material (e.g. leaves, devitalized material).

- 4.9. **Principal Investigator (PI):** The person designated by the Authorized Party as responsible for the entire research activities associated with the GEP material.
- 4.10. **Propagatable material:** Any plant or plant part that can be used in the field to regenerate a whole plant.
- 4.11. **Sanitized:** Determined to be free of all propagatable plant material based on visual inspection.
- 4.12. **Transgenic Event:** Each individual transgenic line produced from the modification of a single plant species using a specific genetic construct.

5. GENERAL REQUIREMENTS

- 5.1. Authorized Party and all other agents acting on behalf Authorized Party shall comply with this SOP.

6. REQUIREMENTS FOR STORAGE OF GEP MATERIAL

- 6.1. The requirements in this section shall be applied to the storage of all GEP material.
- 6.2. The Facility Manager shall ensure the suitability of storage facilities on site or at the containment facilities prior to accepting the shipment of GEP material.
- 6.3. A storage area shall be a fully enclosed space (e.g. filing cabinet, office, closet). Access doors shall be lockable. Windows shall be closed and locked.
- 6.4. A storage area for GEP material (see section 6.3) shall be used exclusively for such articles.
- 6.5. Where a storage area may be used to store multiple samples of one or more experimental GEP lines, each sample shall be stored separately in a sealed container (unit) such as the primary container used for shipment (see SOP NCB/GMP/NO1).
- 6.6. All storage areas and units shall be clearly labeled as containing GEP material in accordance with the requirements of Section 7.
- 6.7. Access to storage areas shall be limited to personnel authorized by the Principal Investigator or Facility Manager.
- 6.8. Areas or units designated for storage of GEP material shall be sanitized prior to, and immediately following, the period of storage.
- 6.9. Any GEP sample withdrawn from storage for the purpose of disposition shall be destroyed by dry heat, steam heat, crushing, burning, or treatment with appropriately labeled herbicides and/or chemicals.

7. LABELING OF STORAGE AREAS/UNITS

- 7.1. A storage area/unit (see section 6.3) shall be labelled as containing GEP material (see Annex 1 for a sample label).

- 7.2. The Storage Area/Unit Label shall be affixed to the point of access to the storage area.

8. INSPECTION OF THE STORAGE AREA

- 8.1. A Record of Storage Inspection shall be completed monthly by the Facility Manager to ensure that storage conditions are maintained in accordance with this SOP.
- 8.2. The Record of Storage Inspection shall be maintained by the Facility Manager in the storage facility's Compliance Document Binder.

9. CORRECTIVE ACTION IN THE EVENT OF AN ACCIDENTAL RELEASE

- 9.1. In the event of a confirmed accidental release of GEP material all attempts shall be made to recover as much of the GEP material as possible. This material shall be destroyed.
- 9.2. The location of an accidental release shall be marked and monitored to ensure that all the GEP material is treated in a manner that ensures that no additional release of material occurs and that all the GEP material arising from the accidental release is destroyed. The period of monitoring will be determined in consultation with NCB.
- 9.3. In the event of a confirmed accidental release during storage, the Facility Manager shall immediately notify NCB and the Authorized Party immediately by telephone and in writing within 24 hours of the accidental release.
- 9.4. The accidental release of GEP material during storage shall be immediately documented by the Facility Manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Facility Manager and copies shall be submitted by facsimile to the Authorized Party and to NCB.

10. RECORD KEEPING

- 10.1. The Facility Manager shall retain the Record of Storage Inspection in the storage facility's Compliance Document Binder.
- 10.2. The Compliance Document Binder shall be available for inspection by NCB regulatory officials upon request.

11. RELATED SOPS

- 11.1. The following SOPs shall also be consulted:
 - 11.1.1. SOP-NCB/GMP/NO1 on Transport of Genetically Engineered Plant Material in Bangladesh.
 - 11.1.2. SOP-NCB/GMP/NO.6 on 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:** _____

ANNEX 1: EXAMPLE OF A STORAGE AREA/UNIT LABEL

RESTRICTED AREA FOR STORAGE OF EXPERIMENTAL GE PLANTS MATERIAL

Facility Name or Code:

Type of GEP Material Stored: (See definition of plant material)

Room Number or Description:

ACCESS TO THIS STORAGE AREA IS RESTRICTED TO PERSONNEL DESIGNATED BY THE PRINCIPAL INVESTIGATOR/FACILITY MANAGER

IN CASE OF EMERGENCY OR DAMAGE TO THE STORAGE AREA, CONTACT THE FACILITY MANAGER IMMEDIATELY.

NAME OF FACILITY MANAGER: _____

ROOM NO: _____

TELEPHONE NUMBER: _____