# MINISTRY OF ENVIRONMENT AND FORESTS (MOEF)

## STANDARD OPERATING PROCEDURE (SOP): NCB/GMP/NO.4

## FOR

## TERMINATION/HARVEST AND DISPOSITION OF GENETICALLY ENGINEERED PLANT (GEP) MATERIAL IN BANGLADESH

### OBJECTIVE/PURPOSE

***To Ensure Compliance with Requirements for Harvest and Disposition 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 at the time of application for a confined field trial.***

### CORRESPONDENCE OR ENQUIRIES

**Secretary**
**National Committee on Biosafety**
**Ministry of Environment and Forests**
**Govt. of the People's Republic of Bangladesh**
**Bangladesh Secretariat**
**Dhaka**

**SOP: NCB/GMP/NO.4**
**TERMINATION/HARVEST AND DISPOSITION OF FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS IN BANGLADESH.**

## 1. DESCRIPTION OF THE ACTIVITY

The appropriate termination/harvest and disposition of field trials of genetically engineered plants 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. **Authorized Party:** The addressee on the notification of authorization. The authorized Party shall accept full responsibility for compliance with all terms and conditions of authorization.

3.3. **Early termination:** Termination of a trial before the anticipated completion date.

3.4. **Field trial:** The planting of one or more genetically engineered plants in a single experiment.

3.5. **Genetically Engineered:** Organisms modified by 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 charged with the responsibility of regulating importation and environmental introduction of any GMO for confined trial and commercial release.

3.8. **Trial Manager:** The party identified to NCB by the Authorized Party as responsible for ensuring the implementation of this SOP.

3.9. **Trial site location**: The geographic location of a trial site as identified by an address, legal land location, or GPS coordinates.

3.10. **Trial site:** The area where one or more field trials are planted and that is reproductively isolated by one continuous method.

## 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 HARVEST OF TRIAL SITES

5.1. The requirements in this section apply to the harvest of trial sites of GEP material, including trial sites that may be prematurely terminated prior to the anticipated harvest date.

5.2. No plant material from the trial site, including non-GEP material from border rows, shall enter the human food or animal feed chains.

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

5.4. All equipment used to harvest a trial site after trial is complete shall be cleaned at the trial site to eliminate unintended transport of GEP materials from the site. Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water.

5.5. 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 labelled herbicides and/or chemicals and disposed of on the trial site in a burial pit.

5.6. The Authorized Party shall arrange with NCB to have a NCB inspector present at time of harvest. This arrangement shall be made in writing at least five (5) working days prior to harvest and confirmed with NCB 24 hours prior to harvest.

5.7. All activities related to harvest of a trial site shall be recorded in the Record of Harvest/Termination and Disposition (NCB/CFT/FORM NO.13).

5.8. No GEP material shall be retained from the trial site without prior authorization from NCB, obtained at the time of application for the confined field trial.

## 6. EARLY TERMINATION OF TRIAL SITES

6.1. Trial sites that are terminated before trial completion (before seed set, before formation of ear, tuber or any reproductive material) shall be destroyed appropriately as described in section 7. The decision to terminate the trial may be taken for different reasons, such as a situation of non-compliance or breach of reproductive isolation, or in the event that the GEP material exhibits characteristics different from those listed in the application or suffers an unusual occurrence.

6.2. In the event of a GEP material exhibiting characteristics different from those listed in the application or suffering an unusual occurrence, the Trial Manager

and/or the Authorized Party shall notify NCB in writing five (5) working days before terminating the trial.

6.3. Post-harvest restrictions shall apply to trial sites that are terminated early as propagatable material of the GEP material may remain from planting and volunteer in subsequent years.

6.4. The Authorized Party shall arrange with NCB to have an NCB-appointed official present at time of termination. This arrangement shall be made any time prior to termination but confirmed with NCB 24 hours prior to termination.

6.5. All activities related to early termination of a trial site shall be recorded in the Record of Harvest/Termination and Disposition.

6.6. No GEP material shall be retained from trial site without prior authorization from NCB, obtained at the time of application for the confined field trial.

## 7. DESTRUCTION OF GENETICALLY ENGINEERED PLANT MATERIAL

7.1. Plant material from a trial site, including border rows, that is not retained for research purposes shall be destroyed by dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labelled herbicides and/or chemicals and disposed of in a burial pit on the trial site.

7.2. The Trial Manager shall monitor harvesting at trial sites to ensure that GEP material that is not retained is disposed of as described in section 7.1.

## 8. TRANSPORT OF HARVESTED MATERIALS FROM THE TRIAL SITE

8.1. All GEP material harvested from a trial site and retained shall be secured during transport from the trial site to the receiving facility to prevent any accidental release.

8.2. The requirements for transport as outlined in the SOP: NCB/GMP/NO1: Transport of Genetically Engineered Plant Material in Bangladesh shall apply.

## 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. 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.

9.3. 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.

9.4. The accidental release of GEP material 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 facsimile to NCB and the Authorized Party.

## 10. RECORD KEEPING

10.1. A Record of Harvest/Termination and Disposition shall be completed by the Trial Manager immediately following harvest or early termination of a trial site. One copy shall be retained by the Trial Manager in the Compliance Document Binder and one copy shall be submitted to the Authorized Party and a copy to NCB within five (5) working days of completion of harvest or early termination.

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: Transport of Genetically Engineered Plant Material in Bangladesh.

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

11.1.3. SOP-NCB/GMP/NO.3: Compliance Management of Current Season Field Trials of Genetically Engineered Eggplant (*Solanum melongena* L.*)* in Bangladesh.

11.1.4. 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:_____**