

MINISTRY OF ENVIRONMENT AND FORESTS (MOEF)

STANDARD OPERATING PROCEDURE (SOP): NCB/GMP/NO.6

FOR

**CONTENTS, PLACEMENT AND RENEWAL OF COMPLIANCE DOCUMENT
BINDER**

OBJECTIVE/PURPOSE

To Ensure Compliance with Requirements for Contents, Placement and Renewal of the Compliance Document Binder 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.

CORRESPONDENCES 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-MOEF/GMP/NO. 6: CONTENTS, PLACEMENT AND RENEWAL OF COMPLIANCE DOCUMENT BINDER.

1. DESCRIPTION OF THE ACTIVITY

Contents, placement and renewal of the Compliance Document Binder.

2. SOP AUTHORIZATION

NCB Authority:

Title:

Signature and Stamp:

Date:

Implementation Date:

In Effect Until:

3. DEFINITIONS

- 3.1. **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.
- 3.2. **Facility Manager:** The 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.
- 3.3. **Field trial:** The planting of one or more regulated articles in a single experiment.
- 3.4. **Genetic Engineering:** The genetic modification of organisms by recombinant DNA techniques.
- 3.5. **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.
- 3.6. **NCB:** Regulatory authority charged with the responsibility of regulating importation and environmental introduction of any GMO for confined trial and commercial release.
- 3.7. **Principal Investigator (PI):** The person designated by the Authorized Party as responsible for the entire research activities associated with the GEP material.
- 3.8. **Trial Manager:** The party identified to the Applicant as responsible for ensuring the implementation of this SOP.
- 3.9. **Trial site:** The area where one or more field trials may be planted and that is confined by one continuous method of reproductive isolation.
- 3.10. **Trial site location:** The geographic location of a trial site as identified by an address, legal land location, or GPS coordinates.

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. CONTENTS OF THE COMPLIANCE DOCUMENT BINDER

- 5.1. A Compliance Document Binder shall be prepared for all the activities of genetically engineered plant material listed in section 5.3.
- 5.2. The Compliance Document Binder shall include:
 - 5.2.1. Section 1. Standard Operating Procedures (SOPs)
 - 5.2.2. Section 2. Records and Reports.
- 5.3. Section 1 of the Compliance Document Binder shall contain copies of the following SOPs:
 - 5.3.1. **NCB/GMP/NO.1:** Transport of Genetically Engineered Plant Material in Bangladesh.
 - 5.3.2. **NCB/GMP/NO.2:** Storage of Genetically Engineered Plant Material in Bangladesh.
 - 5.3.3. **NCB/GMP/NO.3:** Compliance Management of Current Season Field Trials of Genetically Engineered Eggplant (*Solanum melongena* L.) in Bangladesh.
 - 5.3.4. **NCB/GMP/NO.4:** Termination/Harvest and Disposition of Field Trials of Genetically Engineered Plant Material in Bangladesh.
 - 5.3.5. **NCB/GMP/NO.5:** Post-Harvest Management of Field Trials of Genetically Engineered Eggplant (*Solanum melongena* L.) in Bangladesh.
 - 5.3.6. **SOP-NCB/GMP/NO.6:** Contents, Placement and Renewal of the Compliance Document Binder

5.4. Records and reports completed in accordance with the following SOPs shall be retained in Section 2 of the Compliance Document Binder under the following headings:

Activity	Record / Report	NCB-MOEF Identification	Relevant SOP
Transport	Record of Transport w/ Transport Inventory List	NCB/CFT/FORM NO.1	SOP- NCB/GMP/NO.1
	Record of Corrective Action	NCB/CFT/FORM NO.2	
Storage	Record of Storage	NCB/CFT/FORM NO.3	SOP- NCB /GMP/NO.2
	Record of Storage Inspection	NCB/CFT/FORM NO.4	
	Record of Corrective Action	NCB/CFT/FORM NO.2	
Current Season – Eggplant	Record of Planting	NCB/CFT/FORM NO.5	SOP- NCB/GMP/NO.3
	Record of Spatial Isolation	NCB/CFT/FORM NO.6	
	Record of Border Row Isolation	NCB/CFT/FORM NO.7	
	Record of Early Crop Destruct	NCB/CFT/FORM NO.8	
	Record of Corrective Action	NCB/CFT/FORM NO.2	
Harvest & Disposition	Record of Harvest/Termination and Disposition	NCB/CFT/FORM NO.13	SOP- NCB/GMP/NO.4
	Record of Corrective Action	NCB/CFT/FORM NO.2	
Post-Harvest – Eggplant	Record of Post-Harvest Inspection	NCB/CFT/FORM NO.14	SOP-NCB/GMP/NO.5
	Record of Corrective Action	NCB/CFT/FORM NO.2	

5.5. At the end of each calendar year the contents of Section 2 of the Compliance Document Binder shall be archived by the Authorized Party.

5.6. Archived materials shall be maintained for a period of no less than **FIVE (5) YEARS** after which time the materials shall be destroyed.

6. PLACEMENT OF THE COMPLIANCE DOCUMENT BINDER

6.1. Sets of copies of Section 1, which shall be provided by NCB, shall be spiral bound and placed in an accessible location at each facility where GEP material is managed so that it may be reviewed at any time by all personnel involved in the compliance management of the GEP material. The Applicant shall specify the number of sets required at the time of application based on the number of facilities involved.

6.2. A set of copies of Section 1 and Section 2 of the Compliance Document Binder shall be placed in a secure location accessible only to the Authorized Party, Principal Investigator, Trial Site Manager or Facility Manager.

6.3. The Compliance Document Binder shall be available for inspection by FBC-NCB inspectors upon request.

7. REVIEW AND DISTRIBUTION

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

- 7.2. 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.
- 7.3. Archival copies of this SOP shall be maintained by Authorized Party for no less than five years.

8. ASSURANCE

- 8.1. 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:** _____