

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

OBJECTIVE/PURPOSE

To Ensure Compliance with Requirements for Transport of GEP Materials 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/GMP/NO.1**TRANSPORT OF GENETICALLY ENGINEERED PLANT (GEP) MATERIAL****1. DESCRIPTION OF THE ACTIVITY**

The appropriate transport of GEP material within Bangladesh.

2. SCOPE

This SOP will cover GEP material imported into Bangladesh and GEP material transported: to, from or between contained facilities; to, from or between confined field trial sites and contained facilities; and GEP material destined for export.

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 experimental GE plant material in the environment; the human food and/or livestock feed chains.
- 4.2. **Applicant:** A permanent resident of Bangladesh or designated Bangladeshi agent to whom all correspondence with respect to the application for a confined field trial including the notification of authorization shall be addressed.
- 4.3. **Authorized Party:** The addressee on the notification of authorization who shall accept full responsibility and or liability for compliance with all terms and conditions of authorization.
- 4.4. **Event:** Each individual transgenic line produced from the modification of a single plant species using a specific genetic construct.
- 4.5. **Facility Manager:** For the purpose of this SOP, shall be 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.
- 4.6. **Genetically Engineered:** Organisms modified by recombinant-DNA techniques.
- 4.7. **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.
- 4.8. **NCB:** Regulatory authority charged with the responsibility of regulating importation and environmental introduction of any GMO for confined and commercial release.

- 4.9. **Plant material:** Propagatable material (*e.g.*, seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagatable material (*e.g.*, leaves, devitalized material).
- 4.10. **Primary container:** The container into which GEP material is placed.
- 4.11. **Principal Investigator:** The person designated by the Authorized Party as responsible for the entire research activities associated with the confined field trial/trials.
- 4.12. **Propagatable material:** Any plant or plant part that can be used in the field to regenerate a whole plant.
- 4.13. **Recipient:** The responsible party or person identified by Authorized Party for the purpose of transporting the GEP material from the Shipper. For the purpose of this SOP, shall be the Principal Investigator (PI), Trial Manager (TM) or Facility Manager (FM).
- 4.14. **Sanitized:** Determined to be free of all propagatable plant material based on visual inspection.
- 4.15. **Secondary container:** The container into which a primary container is placed.
- 4.16. **Shipper:** The responsible party or person identified by Authorized Party for the purpose of transporting the GEP material from one point to another.
- 4.17. **Tertiary container:** The container into which a secondary container is placed.
- 4.18. **Trial Manager:** The person designated by the PI or Authorized Party as responsible for the activities of the confined field trial/trials.

5. GENERAL REQUIREMENTS FOR THE TRANSPORT OF ALL GEP MATERIAL

- 5.1. The Authorized Party and all other agents acting on behalf of the Authorized Party shall comply with this SOP.
- 5.2. All GEP material shall be stored in secure containers for transportation.
- 5.3. All GEP material shall be kept separate (secured in a primary container) from other plant material during transport.
- 5.4. All GEP material shall be clearly labelled.
- 5.5. The Authorized Party shall ensure that appropriate containers are supplied to all agents working on their behalf for the purpose of transporting the GEP material.

6. SPECIFIC REQUIREMENTS FOR THE TRANSPORT OF GEP MATERIAL

- 6.1. The requirements in this section apply to GEP material, imported into Bangladesh and GEP material transported: to, from or between contained facilities; to, from or between confined field trial sites and contained facilities; and GEP material destined for export from Bangladesh.

- 6.2. The requirements of this section also apply to non-GEP or approved GEP material that will accompany GEP material when transported within the same secondary and tertiary containers.
- 6.3. Any party seeking exception from any provision of this section shall seek approval from NCB at the time of application.
- 6.4. GEP material shall be secured within a primary container as described in 6.5.
- 6.5. Each sealed, primary container shall contain only GEP material of a single type (*e.g.*, seed, tubers, leaf material, budwood/shoots) derived from one line of a single event.
- 6.6. The primary container shall be a bag of no less than 500 gauge (125 μ m) thickness or a sealed envelope or package constructed of tear and moisture resistant material (*e.g.* polythene bags, sealed box).
- 6.7. The primary container shall be placed within a sealed, leak-proof secondary container that shall be contained within a sealed, leak-proof tertiary container. Several or multiple primary containers of GEP material of multiple events may be placed within a single secondary container.
- 6.8. The secondary container shall be resistant to breakage or water damage and shall be constructed of materials such as corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.
- 6.9. The tertiary container shall be resistant to breakage or water damage and shall be constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.
- 6.10. Primary, secondary and tertiary containers used to transport GEP material shall be sanitized prior to filling and after the plant material has been removed, if intended to be re-used. Alternatively, containers may be destroyed by autoclaving or burning.
- 6.11. Any residual GEP material recovered during the process of sanitization 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.
- 6.12. Primary, secondary and tertiary containers shall be labelled in accordance with the requirements of Section 7.
- 6.13. The shipper shall notify the recipient and NCB as outlined in 8.2.3 through fax prior to shipment.
- 6.14. The Authorized Party shall make the necessary prior arrangements and confirm this by telephone 24 hours before shipment, to have a NCB regulatory official present during shipment, if required.

7. LABELLING OF CONTAINERS FOR THE TRANSPORT OF GEP MATERIAL

- 7.1. Primary containers shall be labelled with a user identification number (e.g., event name or number or other unique identifier), the type of GEP material contained within, and the Shipment Number found on the Record of Transport.
- 7.2. The original Record of Transport shall be placed within the secondary container.
- 7.3. All tertiary containers used to transport the GEP material shall be labelled with a Transport Label securely affixed to the outside of the tertiary container. The Transport Label shall identify the shipper and receiver, emergency contact details, and that the container contains GEP material.

8. ACCOMPANYING DOCUMENTATION FOR THE TRANSPORT OF GEP MATERIAL

- 8.1. Where primary containers of GEP material of multiple events are included within a single secondary container, a Transport Inventory List shall be affixed to the Record of Transport.
- 8.2. The following documents shall be signed, dated and secured to/within containers by the Shipper:
 - 8.2.1. The original Record of Transport, with attached Transport Inventory List where applicable, placed within the secondary container.
 - 8.2.2. The Transport Label shall be affixed to the outside of the tertiary container.
 - 8.2.3. The original Record of Transport, with attached Transport Inventory List where applicable, shall be faxed to Receiver and to NCB before being placed within the secondary container.
- 8.3. Copies of all accompanying documents (including Plant Import Permit, Phytosanitary Certificate where applicable) shall be retained by the Shipper in the shipment facility's Compliance Document Binder.

9. RECEIPT OF TRANSPORTED GOODS

- 9.1. When shipments of all GEP plant material are received, the following actions shall be immediately undertaken by the Recipient:
 - 9.1.1. Verification that the Record of Transport listed in paragraph 8.2.1 accompanied the shipment and was duly signed by the Shipper.
 - 9.1.2. If the original Record of Transport, and Transport Inventory List where applicable, listed in paragraph 8.2.1 are absent from the shipment, the Recipient shall contact the Shipper and request copies be transmitted immediately. Consequently the shipper shall notify NCB regarding the absence.

- 9.1.3. Until such time as the original Record of Transport documents are received and the inventory confirmed, materials shall be placed into secure storage (see SOP–NCB/GMP/NO.2) and no further action shall be taken with the materials.
- 9.1.4. Complete the Receipt of Shipment section of the original Record of Transport, including the confirmation that the containers used for transport were not breached.
- 9.1.5. If the tertiary container was breached but the secondary container remained secure no further action is required.
- 9.1.6. If both the secondary and tertiary containers were breached ensure that the primary container was not breached and that none of the seed and/or plant material has been lost by confirming the weight of the shipment or number of plants or items in transit.
- 9.1.7. If it cannot be confirmed that an accidental release of plant material has not occurred, follow the corrective action requirements in Section 10.
- 9.1.8. A copy of the completed Record of Transport document shall be faxed to the shipper and to the Authorized Party, who shall consequently forward the record to NCB.

10. CORRECTIVE ACTION IN THE EVENT OF AN ACCIDENTAL RELEASE

- 10.1. If it cannot be assured that an accidental release of plant material has not occurred during transport, the recipient shall treat this as a case of accidental release and immediately notify the Authorized Party who will initiate appropriate reporting and corrective action notification to NCB for information or any action if required.
- 10.2. 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.
- 10.3. The location of an accidental release shall be marked and monitored to ensure that all the GEP material arising from the accidental release (*i.e.* volunteer plants) is destroyed. The period of monitoring will be determined in consultation with NCB.
- 10.4. In the event of a confirmed accidental release during transport the Recipient shall immediately notify the Authorized Party by telephone who shall notify NCB immediately by telephone and in writing within 24 hours of the accidental release.
- 10.5. The accidental release of GEP material during transport shall be immediately documented by the Recipient in a Record of Corrective Action (NCB /CFT/FORM NO.2). The original Record of Corrective Action shall be retained by the Recipient and copies shall be submitted by facsimile to the Authorized Party who shall ensure that the same records are faxed to NCB.

11. RECORD KEEPING

- 11.1. Copies of the Record of Transport, including the Transport Inventory List if appropriate, as completed by the Recipient shall be forwarded to the Shipper and the Authorized Party who shall ensure a copy is forwarded to NCB. The original copy shall be inserted in the recipient facility's Compliance Document Binder.
- 11.2. The Compliance Document Binder shall be available for inspection by FBC-NCB inspectors upon request.

12. RELATED SOPS

- 12.1. The following SOPs shall also be consulted:
 - 12.1.1. SOP-NCB/GMP/NO.2 on Storage of Genetically Engineered Plant Material in Bangladesh.
 - 12.1.2. SOP- NCB/GMP/NO.6 on 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 the 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 _____

SIGNATURE: _____ DATE: _____