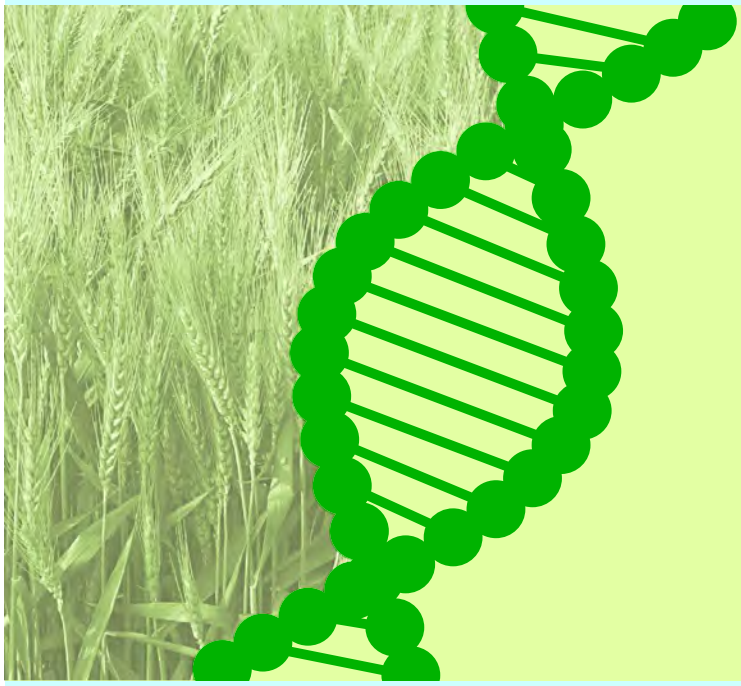

STANDARD OPERATING PROCEDURES (SOPs) FOR CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

STANDARD OPERATING PROCEDURES (SOPs) FOR CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

1. OBJECTIVE

Standard Operating Procedures (SOPs) have been prepared to provide guidance for the following aspects of conducting confined field trials of regulated, genetically engineered crops in India:

1. Transport of regulated GE plant material.
2. Storage of regulated GE plant material.
3. Management of confined field trials.
4. Management of harvest or termination of confined field trials.
5. Post-harvest management of confined field trials.

2. GENERAL REQUIREMENTS

2.1. The Permitted Party and all other agents acting on behalf of the Permitted Party must comply with these SOPs.

2.2. No regulated plant material from the trial site, including material from border rows when used, is permitted to enter the food or feed chains.

2.3. All the relevant Records are to be filled as per the requirements indicated in each SOP. The following formats of records have been enclosed.

i. Record of Transport & Transport Inventory List

ii. Record of Storage

iii. Record of Storage Inspection & Inventory

iv. Record of Planting

v. Record of Spatial Isolation

vi. Record of Harvest/Termination

vii. Record of Post-Harvest Monitoring

viii. Record of Corrective Action

2.4. In situations where it becomes known that there has been non compliance with the terms and conditions of the confined field trial permit due to any reasons, the Permitted Party must inform RCGM/GEAC immediately by telephone and positively within 24 hours in writing. RCGM/GEAC will provide the Permitted Party with the appropriate course of remedial action. The corrective actions should be appropriately recorded as explained in the subsequent sections.

3. TERMINOLOGY

The following terminology has been used in the SOPs

i. **Accidental release:** Any unintended release of regulated plant material into the environment, food and/or feed chains.

ii. **DBT**: Department of Biotechnology.

iii. **DLC**: District Level Committee.

iv. **Event:** A genotype produced from the transformation of a single plant species using a specific genetic construct. For example, two lines of the same plant species transformed with the same or different constructs constitute two events.

v. **Facility In-Charge**: For the purpose of this SOP, shall be the person designated by the Permitted Party as responsible for the storage of the regulated material.

vi. **Field trial:** The planting of one or more regulated events in a single experimental plot.

vii. **GEAC:** Genetic Engineering Approval Committee.

viii. **Genetic engineering:** The technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material (*Rules, 1989*).

ix. **IBSC:** Institutional Biosafety Committee.

x. **Isolation distance**: A spatial separation of the trial site from the nearest plant of the same or related species. Isolation distances are crop specific.

xi. **MEC:** Monitoring cum Evaluation Committee.

xii. **Methods of reproductive isolation:** Means used to prevent movement or dissemination of regulated plant material by pollen or seed from the confined trial site (*e.g*., establishing an area around the perimeter of a trial site that is kept free of any prohibited plants for the period of the trial; terminating a confined field trial before the plants in the trial flower and release pollen).

xiii. **Packaging Material:** The material used to secure regulated, genetically engineered seed or other propagable plant material for the purposes of transport and storage. Examples include polythene bags, seed envelope, cardboard box.

xiv. **Permitted Party:** The sponsoring organization identified on a field trial permit issued by RCGM or GEAC who shall accept full responsibility for compliance with all terms and conditions of the permit.

xv. **Physical landmarks:** Landmarks used to identify or designate boundaries of a confined field trial site (*e.g*., telephone poles, fences, alleys or roads).

xvi. **Plant material:** Propagable material (*e.g*., seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagable material (*e.g*., leaves, tissue samples).

xvii. **Post-harvest period**: A period of time that follows the harvest or termination of a confined field trial when restrictions are imposed on the use of the trial site.

xviii. **Primary container**: The container into which regulated plant material is placed (*e.g*. sealed bag, envelope, polythene bags, cardboard box etc).

xix. **Prohibited plants:** With reference to a confined field trial of a regulated, genetically engineered plant, prohibited plants include volunteers of the trial species and any other plant species that are sexually compatible with the trial species under field conditions.

xx. **Propagable:** Any plant or plant part that can be used to regenerate a whole plant under typical field conditions.

xxi. **Recipient**: For the purpose of this SOP, shall be the Permitted Party, Trial In-Charge or Facility In-Charge.

xxii. **RCGM:** Review Committee on Genetic Manipulation.

xxiii. **Regulated plant:** Any plant produced through genetic engineering, including seed or propagable plant material derived from that plant, which has not been authorized by the Government of India for commercial cultivation pursuant to *Rules, 1989*.

xxiv. **Rules, 1989**: Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells Rules, 1989 conferred by sections 6, 8 and 25 of the Environmental (Protection) Action, 1986.

xxv. **SBCC:** State Biotechnology Coordination Committee.

xxvi. **SAU:** State Agricultural University.

xxvii. **Secondary container**: The container into which a primary container is placed.

xxviii. **Transport In-Charge**: The person identified by the Permitted Party as being responsible for the transport of regulated plant material.

xxix. **Trial In-Charge:** The person/scientist designated by the Permitted Party as responsible for ensuring compliance with the terms and conditions of a confined field trial permit and providing information required by regulatory bodies.

xxx. **Trial site:** A single site where one or more field trials of the same plant species are confined by a shared method of reproductive isolation. For example, three confined field trials of cotton surrounded by a shared 50 m isolation area would constitute a single trial site.

xxxi. **Trial site location**: The geographic location of a confined trial site *e.g.*, village, address and plot number.

xxxii. **Volunteers:** Self-sown plants of the same species as the regulated plant that may germinate and grow on the trial site and/or within the isolation distance.

4. STANDARD OPERATING PROCEDURES

The following SOPs should be followed for conducting the confined field trials of all regulated, genetically engineered plants in India.

A. STANDARD OPERATING PROCEDURE (SOP) FOR THE TRANSPORT OF REGULATED GENETICALLY ENGINEERED PLANT MATERIAL

A.1. Scope

A.1.1. This SOP applies to the transport of regulated, genetically engineered seed or propagable plant material for the purposes of import, export, inter-state movement and intra-state movement.

A.2. General Requirements

A.2.1. All regulated, genetically engineered seed or propagable plant material must be stored in secure containers/packets for transportation.

A.2.2. All regulated, genetically engineered seed or propagable plant material must be kept separate (secured in a primary container) from other plant material during transport.

A.2.3. All regulated genetically engineered seed or propagable plant material must be clearly labelled.

A.2.4. The Permitted Party will ensure that appropriate containers/packaging materials are supplied to all agents working on their behalf for the purpose of transporting regulated, genetically engineered seed or propagable plant material.

A.3. Specific Requirements for the Transport of Regulated Genetically Engineered Plant Material

A.3.1. The requirements of this section also apply to non-regulated seed (*e.g.*, conventional seed or genetically engineered seed that has previously been approved for commercial cultivation in India) that will accompany regulated, genetically engineered seed or propagable plant material when transported within the same secondary container.

A.3.2. Regulated, genetically engineered seed or propagable plant material is to be secured within a primary container as described in A.3.4.

A.3.3. Each sealed, primary container can contain only regulated, genetically engineered seed or propagable plant material derived from one event.

A.3.4. The primary container must be a sealable bag, envelope or package constructed of tear and moisture resistant material (*e.g.*, polythene bags, seed envelope, cardboard box).

A.3.5. The primary container must be placed within a sealable, leak-proof secondary container. Multiple primary containers can be placed within a single secondary container.

A.3.6. The secondary container must be resistant to breakage or water damage and should be constructed of materials such as corrugated fibreboard, corrugated cardboard, wood, or other material of equivalent strength.

A.3.7. Primary and secondary containers used to transport regulated, genetically engineered seed or propagable plant material which are proposed to be re-used must be cleaned after use. Alternatively, primary and secondary containers must be destroyed (by autoclaving or burning).

A.3.8. Any residual seed or propagable material recovered during the process of cleaning must be rendered non-viable by heating, incineration or crushing.

A.3.9. Primary and secondary containers should be labelled in accordance with the requirements of Section A.4.

A.3.10. Prior to sending the material, the Transport In Charge must inform the Recipient of dispatch of the material as outlined in A.5.

A.4. Labelling of Containers

A.4.1. Primary containers should be labelled with an identifying number or name of the regulated plant material (*e.g.*, event name or number or other unique identifier) and the Dispatch Number found on the Record of Transport.

A.4.2. All secondary containers used to transport regulated plant material should be labelled to identify the Transport In Charge and Receiver and their emergency contact details in case of an accidental release.

A.5. Accompanying Documentation for the Transport of Regulated Plant Material

A.5.1. The Transport In-Charge must complete the following sections of the Record of Transport: contact details of Transport In-Charge and Recipient; Regulated Plant Material Identification; Pre-Transport Details; his/her Signature; and date of dispatch.

A.5.2. When multiple primary containers of regulated material are included within a single secondary container, a Transport Inventory List must be attached to the Record of Transport.

A.5.3. The Record of Transport, with attached Transport Inventory List if applicable, must be intimated in writing (email/fax/letter) to the Receiver before the consignment is sent.

A.5.4. The original Record of Transport, with attached Transport Inventory List if applicable, must be placed within the secondary container by the Transport In-Charge.

A.5.5. Copies of the Record of Transport, Transport Inventory List if applicable and other accompanying documents (*e.g.*, Plant Import Permit, Phytosanitary Certificate) must be retained by the Transport In-Charge.

A.6. Receipt of Transported Goods

A.6.1. When a consignment of regulated, genetically engineered seed or propagable plant material is received, the following actions should be undertaken immediately by the Recipient:

i. Confirmation/Verification that the Record of Transport and Transport Inventory List (if applicable) accompanied the consignment.

ii. If the Record of Transport is absent from the consignment, the Recipient must contact the Transport In Charge and request that a copy be sent/transmitted immediately.

iii. Until such time as the Record of Transport is received, the consignment must be placed in storage and no further action shall be taken. When the Record of Transport is received the rest of this SOP shall be followed.

A.6.2. The Recipient shall complete the details regarding Receipt of Consignment section of the original Record of Transport.

A.6.3. If the secondary container was damaged during transport, the Recipient must ensure that the primary container was not damaged and that none of the regulated plant material was lost by confirming the weight of the consignment.

A.6.4. If it is suspected that an accidental release has occurred, the corrective action requirements in Section A.7 must be followed.

A.6.5. A copy of the completed Record of Transport should be sent in writing (email or fax) by the Recipient to the Transport In-Charge.

A.7. Corrective Action In the Event of an Accidental Release

A.7.1. In the event of a confirmed accidental release of regulated, genetically engineered seed or propagable plant material during transport all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by heating, crushing, or burning.

A.7.2. The location of an accidental release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed of by heating, crushing, or burning. The period of monitoring will be determined in consultation with RCGM/GEAC.

A.7.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Recipient and copies will be submitted in writing preferably by fax to the Transport In-Charge, Permitted Party and RCGM/GEAC.

A.7.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

B. STANDARD OPERATING PROCEDURE (SOP) FOR THE STORAGE OF REGULATED GENETICALLY ENGINEERED PLANT MATERIAL

B.1. Scope

B.1.1. This SOP applies to the storage of regulated, genetically engineered plant material in India.

B.2. Specific Requirements for the Storage of Regulated Plant Material

B.2.1. The Permitted Party/Facility In-Charge must ensure the suitability of all storage facilities prior to accepting consignments of regulated plant material.

B.2.2. A storage area must be a fully enclosed space (*e.g.*, boxes, almirahs, cabinets, closet etc) and must be secured by a lockable door. If present, any windows must be closed and locked.

B.2.3. Where a storage area may be used to store multiple samples of regulated plants, each sample should be stored separately in a sealed, labelled container.

B.2.4. All storage areas must be clearly labelled as containing regulated plant material in accordance with the requirements of Section B.3 of this SOP.

B.2.5. Access to storage areas must be limited to personnel authorized by the Permitted Party or Facility In-Charge.

B.2.6. Areas or units designated for storage of regulated plant material must be cleaned immediately following the period of storage.

B.2.7. The addition of regulated plant material to the storage area or removal of regulated plant material from the storage area must be recorded on the Record of Storage Inspection and Inventory.

B.2.8. Any sample of regulated plant material removed from storage for the purpose of disposal must be rendered non-viable by heating, crushing, or burning.

B.3. Labelling of the Storage Area

B.3.1. The storage area must be labelled as containing regulated plant material (see Section B.8 for a sample label).

B.3.2. The storage area label should be affixed to the point of entry to the storage area.

B.4. Inspection of the Storage Area

B.4.1. Inspection of the storage area must be completed monthly by the Permitted Party/Facility In-Charge to ensure that storage conditions are maintained in accordance with this SOP. Each inspection is to be recorded on the Record of Storage Inspection and Inventory.

B.4.2. The Record of Storage Inspection and Inventory is to be retained by the Permitted Party/Facility In-Charge.

B.5. Inspection by Regulatory Officials

B.5.1. Access to the storage facility for the purpose of inspection will be provided to regulatory officials/ monitoring committees upon request for official purposes preferably during regular working hours.

B.6. Occurrence of Non-Compliance

B.6.1. In situations where non-compliance with the terms and conditions of the confined field trial permit is confirmed, the Permitted Party will notify RCGM/GEAC immediately by telephone and positively within 24 hours in writing. RCGM/GEAC will provide the Permitted Party with the appropriate course of remedial action.

B.7. Corrective Action in the Event of an Accidental Release

B.7.1. In the event of a confirmed accidental release of regulated plant material from storage all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by dry heat, steam heat, crushing, or burning.

B.7.2. The location of an accidental release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed of by dry heat, steam heat, crushing, or burning. The period of monitoring will be determined in consultation with RCGM/GEAC.

B.7.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Facility In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

B.7.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

B.8. Sample Storage Area Label

THIS STORAGE AREA CONTAINS REGULATED GENETICALLY ENGINEERED PLANT MATERIAL

Storage Site Address
Room Number or Description:

ACCESS TO THIS STORAGE AREA IS LIMITED TO PERSONNEL DESIGNATED BY THE PERMITTED PARTY:

Name of facility in-charge

Room no.

Telephone number

In case of emergency or damage to the storage area, contact the facility In-Charge immediately

C. STANDARD OPERATING PROCEDURE (SOP) FOR THE MANAGEMENT OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

C.1. Scope

C.1.1. This SOP applies to all confined field trials of regulated, genetically engineered plants in India.

C.2. Requirements for Planting Confined Field Trials (All Crops)

C.2.1. All equipment and tools used to seed or plant confined field trials or used in the maintenance of the trial site must be cleaned on the trial site prior to their removal to eliminate unintended transport of regulated plant material from the trial site. Acceptable methods of cleaning include hand cleaning, compressed air, vacuuming of remaining seed or high-pressure water. Any plant material recovered must be rendered non-viable by burning or burial on the trial site.

C.2.2. A map of the trial site must be prepared by the Trial In-Charge and appended to the Record of Planting. Instructions for the preparation of maps are provided in Box 1.

C.2.3. A Record of Planting must be completed for each field trial site. A copy of the Record of Planting, with the appended map, must be submitted to RCGM/GEAC within seven (7) days following the completion of planting. The original Record of Planting must be retained by the Trial In-Charge, and copies made available to regulatory officials upon request.

C.2.4. The Trial In-Charge must mount a Notice Board at the trial site indicating the purpose and duration of the confined field trials conducted at the trial site and the authorization under which the confined field trials were approved.

C.2.5. The Trial In-Charge must ensure that only personnel authorized by the Permitted Party are permitted on the trial site. A bound book including the name, address and affiliation must be maintained of all personnel who enter the trial site

C.3. Performance Requirements for Confined Field Trials (All Crops)

C.3.1. All corners of each trial site will be clearly marked with reference to physical markers to permit identification of the trial site during the period of the trial and the post-harvest period.

C.3.2. Any plant material removed during maintenance of the trial (*e.g.*, thinning of plantlets or removal of any plant parts) must be rendered non-viable by burning or burial on the trial site.

C.3.3. All confined field trial sites must be reproductively isolated from plants of the same or any other sexually compatible species that are not part of the trial by spatial isolation. Isolation distances are crop specific and the allowable isolation distance will be indicated by RCGM/GEAC in the letter of approval for the confined field trial.

C.3.4. The isolation area must be continuous and completely surround the confined trial site.

C.3.5. The Trial In-Charge must ensure that the trial site and surrounding isolation area are kept free of all prohibited plants by implementing a program of regular monitoring and removal of any prohibited plants (see section C.4).

C.3.6. Any prohibited plants within the isolation area must be removed before they flower.

C.3.7. If any prohibited plants within the isolation area are permitted to flower, a breach of reproductive isolation will have occurred.

C.3.8. Any prohibited plants removed from the isolation distance must be rendered non-viable by burning or burial on the trial site.

C.4. Monitoring of the Field Trial by the Trial In-Charge

C.4.1. The following are requirements when spatial isolation is used to reproductively isolate the field trial:

i. The Trial In-Charge or his/her designate must monitor the trial site at least ONCE EVERY TWO WEEKS from the time of planting until the time of harvest of the trial.

ii. The Record of Spatial Isolation will be used to document all monitoring and field activities needed to demonstrate reproductive isolation of the trial site.

iii. The growth stage of any prohibited plants found on the trial site should be recorded during monitoring. To facilitate this, a growth stage key should be made available to all monitoring personnel to facilitate consistency in identifying growth stages. An example of a growth stage key is provided in Box 2.

C.5. Inspection by regulatory officials

C.5.1. Access to the trial site for the purpose of inspection will be provided to regulatory officials/monitoring committees upon request, for official use only and preferably during regular working hours.

C.6. Corrective Action in the Event of an Accidental Release

C.6.1. In the event of a confirmed accidental release of regulated plant material from the trial site, all attempts shall be made to recover as much of the regulated material as possible. Recovered material will be rendered non-viable by burning or burial on the trial site.

C.6.2. If an accidental release affects an area outside the perimeter of the trial site, that location will be marked, monitored and 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 RCGM/GEAC.

C.6.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

C.6.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

C.7. Record Keeping

C.7.1. The Record of Planting and map for each trial site will be retained by the Trial In-Charge and one copy will be submitted to RCGM/GEAC within 7 days of planting.

C.7.2. As appropriate, original copies of the Record of Spatial Isolation for each trial site will be retained by the Trial In-Charge.

C.7.3. All records associated with the management of confined field trials must be available for inspection by RCGM/GEAC, MEC, State Government Officials, State Agricultural University or their nominee upon request.

C.7.4. At the end of the post-harvest period when all requirements for management of the confined field trial site have been completed, the original copies of all reports related to conduct of the trial will be forwarded to the Permitted Party by the Trial In-Charge.

C.7.5. The Permitted Party will archive copies of the following records for all permitted field trials for a minimum of five (5) years, whether or not the regulated material is authorized for commercial release: Record of Planting, Record of Spatial Isolation, Record of Corrective Action (when applicable).

BOX 1: INSTRUCTIONS FOR PREPARATION OF MAPS

1. Maps of confined field trials must be legible and precise. Maps should be on a blank page with crisp line drawings and block letters. Maps on lined or graph paper, photocopies of road or topographical maps will not be accepted.
2. A map of the trial site will be prepared by the Trial In-Charge and appended to the Record of Planting.
3. Maps must provide sufficient detail to allow regulatory officials to locate each field trial site during the planting season and any required period of post-harvest land use restriction.
4. Maps must provide details on the layout of the site and distances between the field trial site and surrounding features.
5. The dimensions of the trial site and distances to physical landmarks must be accurately reported.
6. The following items shall be included on each map of a field trial site:
   a. Trial In-Charge's name and contact details.
   b. Permit number from the regulatory authority.
   c. Legal or descriptive land location (name of the village, taluka, district, state).
   d. Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.
   e. Total area planted with the regulated material, including negative controls and any border or guard rows when used (acres or square meters).
   f. Label all fields within the isolation area by the common name of the crop.
   g. Indicate any fields of same/related crops that fall within, or border on, the isolation area.
   h. Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, garden, orchard, forests, and woodlots, hedgerows), wherever reasonable.
   i. Planting date.
   j. Compass directions, with North at the top of the page.

BOX 2: KEY TO COTTON GROWTH STAGES

This key is provided to standardize the recording of cotton growth stages when monitoring the trial site.

Growth stage	Days after planting
Emergence	5-15
4th true leaf	20-30
1st square (pinhead)	30-45
1st bloom	50-80
Cut out	80-120
Defoliation	120-170
Harvest	130-180

D. STANDARD OPERATING PROCEDURE (SOP) FOR THE HARVEST OR TERMINATION OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

D.1. Scope

D.1.1. This SOP applies to the harvest or termination of all confined field trials of regulated, genetically engineered plants in India.

D.2. Requirements for Harvest of Confined Field Trials

D.2.1. The requirements in this section apply to the harvest or termination of all confined field trials.

D.2.2. All equipment and tools used during harvest or termination of confined field trials must be cleaned on the trial site prior to their removal to eliminate unintended transport of regulated plant material from the trial site. Acceptable methods of cleaning include hand cleaning, compressed air, vacuuming of remaining seed, and high-pressure water. Any plant material recovered must be rendered non-viable by burning or burial on the trial site.

D.2.3. A Record of Harvest/Termination will be completed for each field trial site. This Record will document the amounts and fate of all harvested material and the disposal of any unwanted plant material on the trial site. The Record of Harvest/Termination must be retained by the Trial In-Charge, and copies made available to regulatory officials/monitoring committees upon request.

D.3. Destruction of Regulated Transgenic Plant Material

D.3.1. Plant material from a confined field trial site, including border rows when these were planted, that is not retained for research purposes will be destroyed by burning or burial on the trial site.

D.3.2. Animal grazing of residual plant material that may remain on the trial site after harvest or termination is prohibited.

D.3.3. The Trial In-Charge must monitor harvest or termination at trial sites to ensure that all regulated plant material that is not retained is disposed of as described in D.2.2.

D.4. Transport of Harvested Materials from the Trial Site

D.4.1. The transport of all plant material from the trial site will be conducted in accordance with the Standard Operating Procedure for the Transport of Regulated Genetically Engineered Plant Material.

D.5. Inspection By Regulatory Officials

D.5.1. Access to the trial site for the purpose of inspection will be provided to regulatory officials/monitoring committees upon request for official purposes preferably during regular working hours.

D.6. Occurrence of Non-Compliance

D.6.1. In situations where non-compliance with the terms and conditions of the confined field trial permit is confirmed, the Permitted Party will notify RCGM/GEAC immediately by telephone and positively within 24 hours in writing. RCGM/GEAC will provide the Permitted Party with the appropriate course of remedial action.

D.7. Corrective Action In The Event Of An Accidental Release

D.7.1. In the event of a confirmed accidental release of regulated plant material all attempts shall be made to recover as much of the regulated material as possible. Recovered material will be rendered non-viable by burning or burial on the trial site.

D.7.2. If an accidental release affects an area outside the perimeter of the trial site, that location will be marked, monitored and 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 RCGM/GEAC.

D.7.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

D.7.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

D.8. Record Keeping

D.8.1. The Record of Harvest/Termination must be completed by the Trial In-Charge immediately after harvest or termination of confined field trials at a trial site. This record must be verified and signed by a member of the Monitoring Agency or any nominee of RCGM/GEAC/SBCC/DLC/SAU authorized by RCGM/GEAC to conduct a trial site inspection during harvest.

D.8.2. A copy of the Record of Harvest/Termination must be submitted to RCGM/GEAC within 15 days of harvest/termination of confined field trials at the trial site. One copy is to be retained by the Trial In-Charge and one copy will be submitted to, and retained by, the Permitted Party

D.8.3. All records associated with the harvest or termination of confined field trials must be available for inspection by RCGM/GEAC, MEC, State Government Officials, State Agricultural University or their nominee upon request.

D.8.4. At the end of the post-harvest period when all requirements for management of the confined field trial site have been completed, the original copies of all reports related to conduct of the trial will be forwarded to the Permitted Party.

D.8.5. The Permitted Party will archive copies of the following records for all permitted field trials for a minimum of five (5) years, whether or not the regulated material is authorized for commercial release: Record of Harvest/Termination, Record of Corrective Action (when applicable).

E. STANDARD OPERATING PROCEDURE (SOP) FOR THE POST-HARVEST MANAGEMENT OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

E.1. Scope

E.1.1. This SOP applies to all confined field trials of regulated, genetically engineered plants during the mandated post-harvest period.

E.2. General Requirements

E.2.1. During the post-harvest period, trial sites cannot be used as pasture for animal grazing as regulated plants may be present as volunteers.

E.3. Requirements for Post-Harvest Management of Trial Sites, Case by Case, as Specified by Regulatory Authorities

E.3.1. The mandatory post-harvest period for confined field trial sites is crop specific and will be indicated by RCGM/GEAC in the letter of approval for the confined field trial.

E.3.2. The post-harvest period begins immediately upon harvest or termination of the confined field trials at the trial site.

E.3.3. Ownership and/or control of the trial site must be secured by the Permitted Party for the post-harvest period. This assurance is to be obtained in writing before the trial site is planted.

E.3.4. During the post-harvest period the trial site may not be planted with the same species as was planted during the confined field trial.

E.3.5. During the post-harvest period, the Trial In-Charge must ensure that any volunteers or prohibited plants are removed from the trial site before flowering and are rendered non-viable by burning or burial on the trial site.

E.3.6. If any prohibited plants are permitted to flower, the post-harvest period will be extended by an additional term equal to the post-harvest period.

E.3.7. Only the trial site will be subject to land use restrictions and monitoring during the post-harvest period, with the following exception: when a breach of reproductive isolation was determined to have occurred in the isolation area during the field trial period the isolation area will also be subject to land use restrictions and monitoring during the post-harvest period.

E.3.8. Post-harvest monitoring and related activities must be recorded in the Record of Post-Harvest Inspection.

E.4. Monitoring of The Post-Harvest Trial Site

E.4.1. During the post-harvest period, the Trial In-Charge must ensure that the trial site is monitored for the presence of volunteers or other prohibited plants at least ONCE EVERY FOUR WEEKS.

E.4.2. At the time of monitoring, the growth stage of any volunteers and/or prohibited plants will be recorded on the Record of Post-Harvest Inspection. To facilitate this, a growth stage key should be made available to all monitoring personnel to facilitate consistency in identifying growth stages. An example of a growth stage key is provided in Box 2.

E.5. Corrective Action In The Event Of An Accidental Release

E.5.1. In the event of a confirmed accidental release of regulated plant material all attempts shall be made to recover as much of the regulated material as possible. Recovered material will be rendered non-viable by burning or burial on the trial site.

E.5.2. If an accidental release affects an area outside the perimeter of the trial site, that location will be marked, monitored and 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 RCGM/GEAC.

E.5.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

E.5.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

E.6. Record Keeping

E.6.1. The Record of Post-Harvest Monitoring will be completed by the Trial In-Charge for the duration of the post-harvest period.

E.6.2. All records associated with the management of confined field trials must be available for inspection by RCGM/GEAC, MEC, State Government Officials, State Agricultural University or their nominee upon request.

E.6.3. At the end of the post-harvest period when all requirements for management of the confined field trial site have been completed, the original copies of all reports related to the trial site will be forwarded to the Permitted Party.

E.6.4. The Permitted Party will archive copies of the following records for all permitted field trials for a minimum of five (5) years, whether or not the regulated material is authorized for commercial release: Record of Post-Harvest Monitoring, Record of Corrective Action (when applicable).

5. REVIEW OF SOPs

5.1. These SOPs will be reviewed by RCGM/GEAC at least annually.

5.2. After review, any revised SOPs will be posted to the DBT website (www.dbtbiosafety.nic.in), provided to all MECs, SAUs, IBSCs, SBCCs and DLCs, and will be referred to in confined field trial permits.

6. CORRECTIVE ACTION IN CASE OF ACCIDENTAL RELEASE

In the event of a confirmed accidental release of regulated plant material at any stage, all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by dry heat, steam heat, crushing, or burning.

The location of an accidental release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed of by dry heat, steam heat, crushing, or burning. The period of monitoring will be determined in consultation with RCGM/GEAC.

The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

Any other corrective actions will be determined in consultation with RCGM/GEAC.