GUIDELINES FOR MONITORING CONFINED FIELD TRIAL OF GENETICALLY ENGINEERED PLANTS IN BANGLADESH

Department of Environment
Ministry of Environment, Forest And Climate Change

Formatted: Font: 14 pt

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

TABLE OF CONTENTS

Glossary of Terms

Accidental release: Any unauthorized release of experimental GE plant material in the environment; the human food and/or livestock feed chains.

Anthesis: The time of flowering. Anthesis is complete when flowering is complete.

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.

Authorized Party: The addressee on the notification of authorization who shall accept full responsibility for compliance with all terms and conditions of authorization.

Devitalized: Non viable or non-reproductive. Devitalization can be achieved through e.g. autoclaving, incineration etc.

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

Event: Each individual transgenic line produced from the modification of a single plant species using a specific genetic construct.

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.

Field Level Biosafety Committee (FBC): Committee operating under the NCB to monitor confined field trials with GE plants to ensure compliance with the terms and conditions of approval for the trials.

Field trial: The planting of one or more GE plants in a single experiment.

Genetically Engineered Plant (GEP) Material: Also referred to as transgenic plant material; for the purpose of this document, 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.

Genetically Engineered (GE): The genetic modification of organisms by recombinant-DNA techniques.

National Committee on Biosafety (NCB): The government authority charged with regulating confined field trials of genetically engineered plants.

Permanent markers or Landmarks: Physical signs or markers used to identify or designate boundaries of a Confined Field Trial (e.g. telephone poles, fences, alleys, roads or steel poles).

Plant material: Propagatable material (*e.g*., seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagatable material (*e.g*., leaves, devitalized material).

Primary container: The container into which GEP material is placed for ttransport.

Principal Investigator: The person designated by the Authorized Party as responsible for the entire research activities associated with the confined field trial/trials.

Prohibited Plants: Specific plants not allowed to grow with a specified distance of the trial site. These include all volunteers of the same species as planted in the confined trial, and closely related crops and weedy relatives.

Propagatable: Any plant or plant part that can be used in the field to regenerate a whole plant.

Reproductive Isolation: Means used to prevent movement or dissemination of genetic plant material by pollen-flow or seed dispersal from the confined field trial site.

Sanitized: Determined to be free of all propagatable plant material based on visual inspection.

Secondary container: The container into which a primary container is placed for transport.

Sexually Compatible: Ability of the GEP material to cross-pollinate with other cultivated plants of the same species, or with wild plants of a related species, and form viable hybrids without human intervention.

Shipper: The responsible party or person identified by Authorized Party for the purpose of transporting the GEP material from one point to another.

Tertiary container: The container into which a secondary container is placed for transport.

Trial Manager: The person designated by the concerned organization or PI or Authorized Party as responsible for managing a confined field trial site.

Trial site: The area where one or more field trials may be planted and that is confined by one continuous method of reproductive isolation.

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

Uninterrupted perimeter border row: A continuous border row of a depth specified by the regulatory authority for each crop of non-transgenic plants of the same maturity as the GE crop planted to provide a pollen trap for the purpose of reproductive isolation.

Volunteers: Plants of the same species as the genetically engineered plant material that germinate and grow in the trial site after termination of the trial.

A. Introduction

Biosafety Guidelines concerning Good Laboratory Practices in handling genetically engineered plants in Bangladesh were approved in 2008. Field trial guidelines for GE plants are yet to be developed, however field trials under approved conditions may be conducted and will require review by authorized monitoring officers. This manual is intended to provide clear and concise instructions to help monitoring officers evaluate confined field trials of genetically engineered plants in Bangladesh. These inspection guidelines consider trials of imported or domestically developed genetically engineered plants conducted in accordance with terms and conditions of authorization.

According to the regulations on confined field trials of genetically engineered plant material, monitoring officers have the authority to inspect confined field trial sites during the current growing season and the period of post-harvest land use restriction for compliance with the terms and conditions of authorization. Monitoring officers also have the authority to inspect contained facilities that may be used for the storage of experimental genetically engineered plant material.

B. Scope

This manual provides background and information on the confined field trial inspection program. It is divided into sections on introduction, purpose, inspection procedures, reporting and communication procedures and appendices. The inspection procedure is intensive and comprises the following:

1. **General requirements:** This section outlines requirements when an monitoring officer is planning for an inspection
2. **Documentation Inspection:** This outlines the kind of documents which should be reviewed as provided for in the Standard Operating Procedures for confined field trials produced by the NCB.
3. **Facility inspection:** This outlines the procedures to be followed if the scheduled inspection will cover inspection of storage facilities.
4. **Transport, Storage and Labelling:** Inspection during transport, storage and for identification purposes is considered separately from facility inspection. This is because these activities may be undertaken separately from facility inspection or at times may be done together.
5. **Field Trial inspection during the growing period**: The requirements for this type of inspection are divided into site location inspection and review of reproductive isolation.
6. **Termination, Harvest and Disposition:** The procedures for an inspection during termination or harvest of a trial and disposition of GEP material are described here.
7. **Post Harvest Site Monitoring:** Procedures for inspection during the post harvest monitoring period.

C. Purpose

This manual is intended for monitoring officers responsible for inspection of Confined Field Trials of Genetically Engineered Plant (GEP) material in Bangladesh. It is intended for instruction and reference and will assist the officers to plan for the inspections following a trial approval or authorization. It details the inspection requirements including performance standards to ensure compliance with regulations governing conduct of confined field trial in Bangladesh. It will guide in the following:

- Conducting field inspections pursuant to application requests and approval.
- Completing appropriate reports and associated inspection checklists and other relevant documents.
- Familiarization with authorization permit conditions .
- Interpreting field site conditions and determining if the site or facility is in compliance.
- Educating researchers, applicants and public to enhance self compliance.
- Learning frequently used terms of Confined Field Trial authorization permits.
- Enforcing Confined Field Trial regulations for genetically engineered plant material.
- Developing self compliance with applicants, authorized parties and all involved in the conduct of the confined field trial.

D. Terms of Reference for Monitoring Officers

Monitoring officers will be delegated with authority by NCB to undertake monitoring of confined field trial sites, or storage facilities, for the purpose of ascertaining compliance with the terms and conditions of authorization. Monitoring officiers will be issued official letters identifying them as such for monitoring confined field trials or related activities. A copy of this letter will also be sent to the Authorised Party and these credentials must be available for presentation to the Trial manager, or during the site visit. The following terms of reference shall apply to all monitoring officers.

Ethical Conduct
Trust, integrity, confidentiality and discretion are essential to monitoring activities and all monitoring officers shall conduct themselves in a professional and ethical manner. All information and documents, including working drafts and any reports, shall be considered confidential. Monitoring officers shall not release any information or documents to any third party without the prior written permission of the NCB.

Fair Presentation
The findings, conclusions and reports of monitoring officers will truthfully and accurately reflect the monitoring activities. Significant obstacles encountered during site visits and unresolved diverging opinions between the monitoring officer and the Authorised Party will be recorded in the final report.

Due Professional Care
Monitoring officers will exercise care in accordance with the importance of the task they perform and the confidence placed in them by the NCB Having the necessary competence is a prerequisite for participation as a monitoring officer and the head of the monitoring team will be responsible for ensuring that all individuals designated as monitoring team members have necessary professional expertise.

Independence
Monitoring officers should be independent of the activity being inspected and free from bias and conflict of interest. Monitoring officers must maintain an objective state of mind throughout the monitoring process to ensure that the findings and conclusions will be based only on the observations during their visit.

Evidence-based Approach
Reports of monitoring officers, upon which conclusions and regulatory actions may be based, must be verifiable. Such evidence may include photographs of trial site conditions, measurements of trial site dimensions and isolation distances, samples of documents and/or records, and first-hand interviews with technical personnel.

E. Inspection Procedure

General Requirements

1. An inspection package comprising of the following documents will be provided to the monitoring officer.
    - Regulations governing conduct of Confined Field Trials in Bangladesh
    - The Standard Operating Procedures (SOPs) and the relevant recording forms provided to the Applicant/Authorized Party after trial authorization,
    - The Authorization permit including the terms and conditions of authorization plus the trial protocol,
    - The Manual including the reporting documents (checklists/forms) annexed to the manual.
    - Other accessories (Access to digital camera, standard field measuring tape, overcoat etc.)
2. Consequently, the monitoring officer should clearly read and understand the documents provided and consult where clarification is required. The monitoring officer will keep copies of these documents for reference at all times.
3. The standard inspection checklists/forms are to be used during the inspection in addition to inspection and verification of records of various activities in line with the SOPs. Consequently, the monitoring officer will be expected to understand the purpose of each inspection prior to the inspection.
4. The monitoring officer must evaluate previous inspection reports and carry a copy if necessary.
5. The monitoring officer will have a copy of the confined field trial map which clearly shows the following;

- The name and phone number of the manager or field contact.
- The general location of the trial (city/town/region).
- Compass directions, with North at the top of the page.
- Dimensions of the trial site with indication of permanent markers used for precise location of the site, both for current year and post-trial restriction periods.
- Indication of surrounding crops, particularly those that may lie within the spatial isolation distance.
- The authorization reference number provided at time of application.
- The commencement date of the trial.

6. The monitoring officer or supervisor will contact the Authorized Party or Trial Manager to schedule an inspection after approval by the NCB/FBC. If the Authorized party initiates the inspection, the monitoring officer will receive instructions from the same office. Follow-up inspections to ascertain implementation of recommendations after a previous inspection may not require approval from the NCB/FBC.
7. The inspection may be scheduled at any time but preferably prior to shipping for certification of storage facilities and for confined field trials; at planting, prior to flowering, at harvest and during post harvest land use restriction.
8. The monitoring officer will take measurements of the following whenever applicable; trial site, isolation distance and border rows during inspection as well as recording any volunteers or prohibited plants.
9. Prompt and accurate reporting by the inspecting officer will be required to enable the NCB/FBC to respond promptly without delay to cases of non compliance or violations. For cases that require immediate attention to bring the trial back to compliance, the monitoring officer must give appropriate advice and notify the NCB/FBC immediately.

Documentation Inspection

Inspection of the documentation alone may be scheduled by the monitoring officer when necessary or may be combined with any of the other type of inspections. The monitoring officer may inspect the documentation before or after inspecting the field trial. This inspection is for verification purposes in line with the requirements of the SOPs. The monitoring officer will interview the facility manager or trial manager in addition to perusal and inspection of the records. The documentation to look for is as detailed below:

1.1. Transport documentation
  1.1.1. Record of Transport
  1.1.2. Genetically Engineered Material Identification information
1.2. Storage documentation
  1.2.1. Record of Transport
  1.2.2. Record of Storage Inspection by the Facility Manager
2.3 Current season documentation
  2.3.1 Record of Planting

2.3.2 Record of Spatial Isolation
2.3.3 Record of any other Reproductive Isolation used on the trial
- Border Row Isolation
- Temporal isolation
- Detasseling/Deflowering
- Bagging
- Early Crop Destruct

2.4 Termination/Harvest and Disposition Documentation
2.4.1 Record of Termination/Harvest and Disposition
2.5 Post Harvest Land Use Restriction and Monitoring
2.5.1 Record of Post Harvest Inspection
2.6 Corrective Action Documentation
2.6.1 Record of Corrective Action
2.7. Compliance Document Binder

Storage Facility Inspection

The facilities may be at the trial site or outside the trial site in a containment facility. Facilities intended to be used for storage of GEP material before planting, during current growing season or after harvest may be inspected at various times. If the material will not be planted immediately on arrival, the facility inspection and subsequent certification should be completed before planting material arrives. Facility inspection may be done prior to harvest. Subsequent inspection may be combined with field trial inspection if the facility is at the trial site. However, specific facility inspections may be planned to check for compliance or when found necessary. The monitoring officer will use the section on facility physical inspection of the checklist for inspection of storage facility; transportation; storage and labeling of genetically engineered plant material (Annex I).

Transport, Storage and Labelling

For inspection of transport, storage and labeling, the monitoring officer will use the checklist for inspection of storage facility; transportation; storage and labeling of genetically engineered plant material (Annex I).

Shipping

The monitoring officer may be required to be present during shipment. The officer should be familiar with the requirements for transport of GEP material and the appropriate records for transport must be inspected and verified in accordance with the requirements of the SOP for transport of GEP material in Bangladesh.

Storage

- The storage facility on site or at the containment facilities must be suitable for storage prior to shipment of GEP material. The officer should be familiar with the requirements for transport of GEP material and the appropriate records for transport must be inspected and verified in accordance with the requirements of the SOP for transport of GEP material in Bangladesh.

Labelling and Other Identification

Proper labeling of containers is critical to ensuring that GEP material is prevented from entering the environment in an uncontrolled manner. The following conditions are part of the standard operating conditions for transport and storage

- Primary containers must be labeled with the type of GEP material contained within, and with the Shipment Number found on the Record of Transport.
- The original Record of Transport must be placed within the secondary container.
- All tertiary containers used to transport the GEP material must be labeled with a Transport Label securely affixed to the outside of the tertiary container.
- Where primary containers of GEP material of multiple events may be included within a single secondary container, a Transport Inventory List must be affixed to the Record of Transport.
- A storage area/unit must be labeled as containing GEP material.
- The Storage Area/Unit Label must be affixed to the point of access to the storage area.
- The Shipper must secure copies of Plant Import Permit and Phytosanitary Certificate within containers.

The condition of the shipping containers must be checked upon arrival at destination. If the tertiary container (where applicable) was breached but the secondary container remained secure no further action is required. If both the secondary and tertiary containers (where applicable) were breached, the monitoring officer should 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 material.

Field Site Inspection During the Growing Period

The trial protocol approved by the NCB in the application should be used as the basis for the inspection. This protocol details the activities required to meet the performance standards for the GEP material under trial. The performance standards depend on biology of the crop in question and the field site location. The most critical performance element is to ensure that the GEP material does not hybridize or pollinate sexually compatible plants that are nearby. These sexually compatible plants include cultivated plants, feral species or wild relatives. The monitoring officer will use the field site inspection checklist (Annex II).

Site Location

- All four corners of each trial site must be clearly marked with permanent markers suitable to permit identification of the trial site.
- Establish whether location of the trial is actually the site identified on the map.
- Reconcile the findings at the trial site with details provided in the map.

Reproductive Isolation

The field trial site of GEP material must be reproductively isolated from any sexually compatible species, sub-species or varieties that are not part of the trial by the reproductive method identified in the trial protocol. A single field trial site must be reproductively isolated in its entirety by no less than one continuous method of reproductive isolation. This minimizes possibility of the GEP material hybridizing or pollinating sexually compatible plants that are nearby. The methods used will vary with biology of crop. The methods can be used sometimes in combination to further minimize risk of pollination.

1. **Spatial isolation**

- When spatial isolation is used as a method of reproductive isolation, GEP material must be separated from other related species by a minimum isolation distance (see Annex III). The monitoring officer should confirm that the spatial isolation distance is continuous and completely encloses the confined trial.
- The trial site and surrounding isolation distance must be kept free of all related non-GE plant species including volunteers. Any plant material found within the isolation distance must be removed before anthesis. The monitoring officer should note any prohibited plants and review records of monitoring to confirm that the isolation has been kept free of prohibited plants
- Plant material removed from the isolation distance must be destroyed using the acceptable disposition protocols. Records of the destruction of the material should be inspected to confirm this.
- The appropriate record of monitoring forms must be inspected and verified in accordance with the requirements of the SOP for compliance management of current season field trials of GEP material.
- It should be noted that other acceptable protocols exist in lieu of the minimum isolation distance and therefore minimum isolation distances for all crops may not be available. However, the monitoring officer should consult regarding issues of crops with unknown isolation distances.

2. **Border Row**

- When a border row is used as a method of reproductive isolation, field trials of GEP material must be isolated from sexually compatible species by planting an uninterrupted perimeter border row of non-GEP material at a planting density comparable to the GEP material. The monitoring officer should confirm that the border row is continuous and completely encloses the test plot. The border is expected to trap or physically prevent the pollen from leaving the test plot. The depth of the border row must be in compliance with what was approved in the trial protocol.
- The border row of non-GEP material must be planted with a plant variety or species that will mature concurrently with the GEP material and be managed using standard agronomic practices.
- The anthesis or flowering of the GEP material must be concurrent with anthesis or flowering of the plants in the border row. The monitoring officer should review records of the flowering of the border row to confirm this.

- If the integrity of the border row is compromised (e.g. wide gaps due to failed germination etc) and cannot be re-established (e.g. by gapping, early replanting), a breach of reproductive isolation will have occurred and must be re-established by spatial isolation where the conditions for spatial isolation can be met.
- Where reproductive isolation of the GEP material cannot be re-established by spatial isolation, the monitoring officer should recommend that the trial be terminated.
- Where border rows are used for reproductive isolation, the growth stage of GEP material and non-GEP border row must be recorded during inspection.
- The appropriate monitoring records for border row isolation must be inspected and verified in accordance with the requirements of the SOP for compliance management of current season field trials of GEP material.

3. Detasseling/Removing flowers

- When detasseling or deflowering is used as a method of reproductive isolation, tassels/flowers of GEP must be removed prior to anthesis/flowering. The monitoring officer should review records of this activity to confirm that is has taken place.
- Where GEP are not detassled/deflowered prior to anthesis, reproductive isolation of the GEP must be re-established by spatial isolation if the conditions for spatial isolation can be met.
- Where GEP are not detasseled/deflowered prior to anthesis/flowering, and reproductive isolation of the GEP cannot be re-established by spatial isolation, the monitoring officer should recommend that the trial be terminated.
- The appropriate records of detasseling/deflowering must be inspected and verified in accordance with the requirements of the SOP for compliance management of current season field trials of GEP material.

4. Early Crop Destruction

- Where early crop destruction is used as a method of reproductive isolation field trials of GEP must be terminated or destroyed prior to inflorescence emergence to ensure no pollen release. This should be indicated in the trial protocol. The monitoring officer should confirm whether plants were destroyed or removed from the field site before any flowers were formed or before pollen was released
- The growth stages of the GEP must be monitored for inflorescence emergence.
- The appropriate records of crop destruction must be inspected and verified in accordance with the requirements of the SOP for compliance management of current season field trials of GEP material.

5. Other methods

- Bagging of flowers or tassels of GEP material to prevent open pollination. The monitoring officer should confirm that quality bagging material has been used that is resistant to tearing or damage to ensure no pollen escape.

- The appropriate records of bagging must be inspected and verified in accordance with the requirements of the SOP for compliance management of current season field trials of GEP material.

Termination, Harvest and Disposition

The monitoring officer may be required to be present during harvest or termination of the field trial to ensure that the specific conditions related to the harvesting and disposal of the material are followed. The most critical aspect is to ensure that no plant material from the site, including non-GEP material, enters the human food or animal feed chain. The checklist in Annex II should be followed by the monitoring officer.

- The monitoring officer should confirm that all equipment used to harvest the trial site is free of plant material before entering the trial site, including seed and vegetative material that may be present from prior operations, and also that the equipment is cleaned on the trial site after harvest to eliminate unintended transport of GEP material from the site. If trials are harvested by hand, the monitoring officer should confirm that clothing is free of material after harvest.
- The monitoring officer should confirm that any residual plant material recovered during the process of cleaning and all other plant material from a trial site, including border rows, that is not retained for research purposes is destroyed by approved methods and disposed of on the trial site.
- All GEP material harvested from a trial site and retained must be secured during transport from the trial site to the receiving containment facility to prevent any accidental release. The Monitoring officer should confirm that GEP material is transported in containers that are recommended for transport of GEP material and as outlined in the SOP for transport of GEP material.
- GEP material from trial site should only be retained with prior authorization obtained at the time of application. The monitoring officer should confirm this by review of the approved field trial application
- If the monitoring officer is not present at the harvest/termination of the trial, the appropriate records for termination/harvest and disposition must be inspected and verified in accordance with the requirements of the SOP for termination/harvest and disposition of GEP material.

Post Harvest Site Monitoring

During the period of post harvest land use restrictions (see Annex IV), the test site should be monitored to remove any volunteer plants, whether they are GEP or not. Inspections during this period will focus on the regular monitoring of the site to make sure that any volunteer plants are removed prior to flowering. The Monitoring officer should first establish which part of the trial site and surroundings are included in the post harvest monitoring area. Only the trial site itself is subject to land use restrictions unless a breach of reproductive isolation has occurred, in which case the whole area of spatial isolation may also be subject to post-harvest restrictions.

- The monitoring officer should confirm that the field site is marked according to the trial protocols with permanent markers at all four corners of each trial site to

permit identification of the trial site during the mandated period of post-harvest land use restriction. Global Positioning Satellite (GPS) position locators may be used to for identification where applicable.

- Post-harvest restrictions will also apply to trial sites that are terminated early as propagatable material of the GEP material may remain from planting and volunteer in subsequent years.
- The monitoring officer should confirm that the trial site has been inspected for the presence of volunteers or sexually compatible species during the period that post-harvest land use restrictions are in effect, and that all volunteers and other prohibited plants have been eliminated from the trial site before anthesis.
- The monitoring officer should confirm, by examination of disposal records that no GEP material or related species from trial sites has entered the human food or animal feed chains. The plant material must be destroyed by roguing, dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labeled herbicides and/or chemicals and disposed of on the trial site in a designated area.
- If any prohibited plants of the GEP material or related species have been permitted to complete anthesis, a breach of reproductive isolation will have occurred and the monitoring officer should recommend that the period of post-harvest restriction must be extended.
- At the time of inspection the growth stage of any prohibited plants must be recorded in the record of post harvest inspection. Inspection of this record will be done and verified in accordance with requirements of SOP for appropriate post harvest management of field trials of GEP material in Bangladesh.

F. Reporting and Communication Procedures

Reports must be written promptly to facilitate immediate decision-making and remedial action. Reports will be forwarded to the NCB/FBC within 24 hours who will consequently officially communicate to the authorized party, giving a copy to the trial manager within 48 hours. For infractions requiring immediate action, the trial manager should be advised accordingly and the NCB/FBC informed on action taken immediately by telephone. Details will consequently be included in the report. An informal working relationship between monitoring officer and the trial manager may be encouraged for enhanced compliance. The trial manager may contact the monitoring officer for consultation. The monitoring officer may carry out unplanned follow-up inspections for ascertaining implementation of recommendations from previous' inspections. In case of follow-up inspections, reports must be written and submitted to NCB/FBC.

G. Appendices

Annex I: Checklist for Inspection of Storage and Transportation of Genetically Engineered Plant Material

Annex II: Checklist for Inspection of Confined Field Trial Sites

Annex III: Some Examples of Minimum Isolation Distances

Plant Species	Minimum Isolation Distance (meters)
Solanum melongena L. (Eggplant)	300*
Gossypium hirsutum (cotton)	400*
Zea mays (maize)	400*
Cicer arietinum L. (Chickpea)	3-5*
Carica papaya L. (Papaya)	1000**
Solanum tuberosum L. (Potato)	20***

* Based on requirements for breeders' seed production.

** Bagging buds of hermaphrodite plants is an acceptable physical method to achieve reproductive isolation.

*** Potato is usually vegetatively propagated so this figure is based on experimental methods of pollen flow distance instead of requirements for breeders' seed production

Annex IV: Some Examples of Post Harvest Land Use Restriction Periods

Plant Species	Post-Harvest Period	Monitoring Interval
Gossypium hirsutum (cotton)	1 year	Every 4 weeks
Zea mays (maize)	1 year	Every 4 weeks
Solanum tuberosum (Potato)	1 year	Every 4 weeks
Solanum melongena (eggplant)	3 months	Every 4 weeks
Cicer arietinum (Chickpea)	1 year	Every 4 weeks
Carica papaya (Papaya)	1 year	Every 4 weeks

Annex VI: Some Examples of Non-Compliance with Recommended Actions

Type of Non-Compliance	Advice	Comments
Current Year Inspections		
Guard row/Border row breakdown.	Fall back to isolation distance.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Insufficient Isolation Distance.	Increase the distance and install new permanent markers if circumstances allow and if crop has not flowered.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Prohibited species within the trial site.	Treat them as GEP material, destroy before flowering.	
Prohibited species within the isolation distance (cultivated plants volunteers or weeds).	Remove before flowering/anthesis.	
Prohibited plants allowed to flower and complete anthesis.	Advise as appropriate depending on stage of growth of GEP material, may require increased post harvest monitoring or termination of trial.	A breach of reproductive isolation requiring follow-up, especially with regard to post-harvest monitoring.
Insufficient tenting (damage, delayed setting up).	Advice as appropriate depending on stage of growth of GEP material. Tent must be set up or repaired before plants flower or fall back to isolation distance .	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Torn bagging material used to cover flowers	Bags replaced immediately, fall back to isolation distance if plants already flowering.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Border rows not flowering.	Fall back to isolation distance.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated
Plants flowering, prior to detasseling/deflowering.	Fall back to isolation distance	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated
Unauthorized trials.	Trial should be terminated.	
Post Harvest Inspection		
Prohibited species within restricted area.	Remove plants and destroy by appropriate method.	
Prohibited plants allowed to set seeds	Remove plants and destroy by appropriate method. Site subject to increased post-harvest monitoring restrictions.	Post-harvest monitoring period may be extended.

Type of Non-Compliance	Advice	Comments
Inspection of Disposal, Storage and Records		
Poor records	Reconcile this with trial performance. The record may indicate poor trial management	Warning letter to authorized party
Storage of GEP material in leaking or non-labeled containers	Recover spilled material, destroy and clean or monitor site for volunteers. Initiate appropriate labeling immediately.	Follow-up inspections may be necessary
Spills at disposal site	Recover spilled material, destroy and clean or monitor site for volunteers. Initiate appropriate labeling immediately.	Follow-up inspections may be necessary