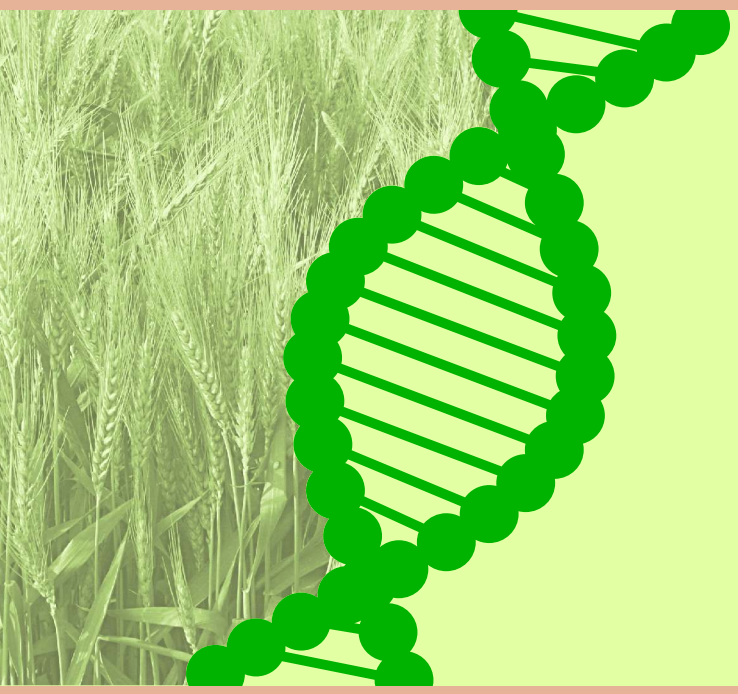

GUIDELINES FOR THE MONITORING OF CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

GUIDELINES FOR THE MONITORING OF CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

1 INTRODUCTION

The conduct of confined field trials of regulated genetically engineered plants in India is regulated under the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells" notified under the Environment (Protection) Act, 1986, commonly referred as Rules, 1989. These rules are implemented by the Ministry of Environment and Forests (MoEF) and Department of Biotechnology (DBT) and State Governments. Six competent authorities have been provided for in the Rules: the Recombinant DNA Advisory Committee (RDAC), the Review Committee on Genetic Manipulation (RCGM), the Genetic Engineering Approval Committee (GEAC), Institutional Biosafety Committees (IBSCs) attached to every organization engaged in recombinant-DNA research, State Biotechnology Coordination Committees (SBCCs) and District Level Committees (DLCs). While the role of the RDAC is strictly advisory in nature, RCGM and GEAC have regulatory responsibilities.

Some of these organizations have been delegated authority under the Rules, 1989 to monitor confined field trial sites for the purpose of ascertaining compliance with the terms and conditions of authorization. These include members of the RCGM's Monitoring cum Evaluation Committee (MEC), SBCCs, DLCs, and monitoring teams of state agricultural universities (SAUs). Monitoring may be undertaken at various times during the conduct of a confined field trial, including during planting, during the growing season, at harvest, and during the period of post-harvest land use restriction. Monitoring agencies also have the authority to inspect contained facilities that may be used for the storage of regulated genetically engineered plant material.

The purpose of these guidelines is to provide clear and concise information to help those individuals designated as members of monitoring teams in the aforementioned monitoring agencies.

2 SCOPE

This document provides information about program for monitoring of confined field trials of regulated genetically engineered plants in India. The information provided herein is intended to provide guidance to designated members of monitoring teams who have been given responsibility of determining whether the conduct of a confined field trial, including the condition of the trial site, or storage facility, and availability of relevant documentation and records, are in compliance with the terms and conditions of *permit.* The guidance contained in this document is consistent with the "Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants in India" and related Standard Operating Procedures (SOPs).

3 TERMINOLOGY

Accidental release: Any unintended release of regulated plant material into the environment, food and/or feed chains. For the purposes of these Guidelines, any breach of the authorized terms and conditions for reproductive isolation of the confined trial site shall be considered an accidental release. Accidental release also includes the spillage, theft, or encroachment by unauthorized persons of regulated GE plant material during transportation, storage within a contained facility, or during any other activity associated with the conduct of a confined field trial. Any accidental release shall be subject to risk assessment, and any necessary corrective actions shall be at the cost of the applicant or permitted party.

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

Applicant: The Applicant must be a permanent resident of India or must designate an Authorized Signatory (AS) who is a permanent resident of India. Where an AS is used, there must be a formal, legal agreement indicating the AS is acting on behalf of the Applicant and both under the jurisdiction of any Court of Law of India. A copy of this agreement must be submitted to the Regulatory Authorities along with the confined field trial application. The Applicant need not be the breeder/developer or owner of the regulated plant, in which case a signed statement is required from the breeder/developer or owner authorizing representation by the Applicant or the designated AS. All correspondence with respect to the application for a confined field trial, including the notification of authorization, will be addressed to the Applicant, or when appropriate, the AS.

Breach: Any contravention or violation of any term and/or condition of authorization of a confined field trial will be considered a breach under these guidelines.

Confined Field Trial: A confined field trial is a field experiment of a regulated GE plant under terms and conditions that are intended to mitigate the establishment and spread of the plant. A single confined field trial may be comprised of one or more varieties/hybrids of a single event of a single plant species that are subject to the same terms and conditions of confinement which include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. The field trials are categorized into two types: Biosafety Research Level I and Biosafety Research Level II trials.

Construct: An engineered DNA fragment containing, but not limited to, the DNA sequences to be integrated into the genome of the target plant.

Early termination: Any termination of a confined field trial before the anticipated completion date.

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.

Facility In-charge: The person designated by the permitted party as responsible for the storage (before or at planting, during planting and after harvest) of regulated, genetically engineered plant material.

Isolation distance: A mandated distance used to spatially separate a confined field trial from the nearest plant of the same or any sexually compatible species. Minimum spatial isolation distances vary depending on the reproductive biology of the plant species, and minimum distances for a number of plant species have been established by the RCGM.

Permitted Party: The Applicant or designated AS will be considered the 'Permitted Party' for the purposes of authorization and is the person who shall accept responsibility for compliance with the terms and conditions of the permit. The 'Permitted Party' may designate a Trial-in-Charge, who will be responsible for ensuring compliance with the requirements of authorization as specified by the Regulatory Authority.

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

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

Prohibited plant: Plants of any species that are sexually compatible with the regulated plant under field conditions, including volunteers that may arise in the isolation area during the conduct of confined field trials.

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

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 Regulatory Authorities for commercial cultivation pursuant to the Rules, 1989 of the Environmental Protection Act, 1986.

Regulatory Authority: As regards confined field trials, RCGM is the regulatory authority responsible for authorizing Biosafety Research Level I trials and GEAC is the regulatory authority responsible for authorizing Biosafety Research Level II trials.

Reproductive isolation: Refers to the means used to prevent movement of plant material, particularly pollen, from a confined field trial site.

Sexually compatible: Ability of a plant 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.

Trial In-charge: The technical person designated by the Permitted Party as responsible for management of the field trial, ensuring compliance with the terms and conditions of a confined field trial authorization and providing information required by Regulatory Authorities. The Trial-in-Charge must, at a minimum, be an agriculture graduate.

Trial site: The area where one or more confined field trials of the same plant species may be grown.

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

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 TERMS OF REFERENCE FOR MONITORING TEAMS

Monitoring teams may be constituted by RCGM/GEAC or any of the agencies delegated with authority by GEAC to undertake monitoring of confined field trial sites, or storage facilities, for the purpose of ascertaining compliance with the terms and conditions of authorization. These bodies may include the MEC, SBCCs, DLCs, and monitoring teams of state agricultural universities (SAUs). Individuals included in monitoring teams will be issued official letters identifying them as Members of the team for monitoring confined field trials or related activities. A copy of this letter will also be sent to the Permitted Party and these credentials must be available for presentation to the Trial In-charge, or Facility In-charge, during the site visit.

The following terms of reference shall apply to all members of monitoring teams.

4.1 Ethical Conduct

Trust, integrity, confidentiality and discretion are essential to monitoring activities and all members of monitoring teams shall conduct themselves in a professional and ethical manner. All information and documents, including working drafts and any reports, shall be considered confidential. The person heading the monitoring team or its members shall not release any information or documents to any third party without the prior written permission of the Regulatory Authorities.

4.2 Fair Presentation

The findings, conclusions and reports of monitoring teams will truthfully and accurately reflect the monitoring activities. Significant obstacles encountered during site visits and unresolved diverging opinions between the monitoring team and the Permitted Party will be recorded in the final report.

4.3 Due Professional Care

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

4.4 Independence

Members of the monitoring teams should be independent of the activity being inspected and free from bias and conflict of interest. Team members 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.

4.5 Evidence-based Approach

Reports of monitoring teams, 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.

5 PROCEDURES FOR MONITORING TEAMS

The monitoring procedures are intensive and comprise the following:

1. **Preparation for the site visit:** This section outlines requirements for planning for a site visit and is applicable to all types of monitoring activities.
2. **Documentation inspection:** This outlines the kind of documents to be inspected in accordance with DBT's Standard Operating Procedures for Confined Field Trials of Genetically Engineered Plants.
3. **Storage facility monitoring:** This outlines the procedures to be followed for monitoring storage facilities, which may be located at the trial site and/or at a laboratory, greenhouse or other facility.
4. **Transport, storage and labelling:** Monitoring related to transport and/or storage. For identification purposes this is considered separately from facility inspection as these activities may be undertaken separately.
5. **Field trial monitoring during the growing period:** The requirements for this type of monitoring are divided into site location monitoring and monitoring for reproductive isolation.
6. **Termination, harvest and disposition:** The procedures entailing activities following termination or harvest of a trial and disposition of regulated genetically engineered plant material.
7. **Post-harvest site monitoring:** The procedures for monitoring trial sites during the period that mandated post-harvest land use restrictions are in effect.

5.1 Preparation For The Site Visit

Generally, visits by monitoring teams should be arranged in advance through communication with the Permitted Party, Trial In-charge or Facility In-charge. Prior to conducting any assessment, the members of the monitoring team should review and understand the following:

1. The Guidelines for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India;
2. Standard Operating Procedures or performance standards implemented during conduct of the field trial;
3. Terms and conditions of authorization attached to the letter of permit; and
4. Any applicable prior monitoring reports.

The following general requirements also apply:

1. In addition to material for recording observations (*i.e.* checklists and/or monitoring forms), accessories such as a measuring tape etc. may be required depending on the audit activity.
2. In the case of monitoring of confined field trial sites, monitoring teams will have a copy of the confined field trial map which clearly shows the following;

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 (hectares 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.

3. After the Regulatory Authority has requested monitoring, the leader of the monitoring team or his authorized representative will contact the Permitted Party, or Trial In-charge, or Facility In-charge as appropriate, to schedule a site visit. If the Permitted Party, or its designate, has requested for the inspection, the monitoring teams will receive instructions from the Regulatory Authority. Follow-up monitoring to ascertain implementation of recommendations and/or corrective actions arising from a previous site visit may not require approval from the Regulatory Authority.

4. Prompt and accurate reporting by the monitoring teams is required to enable the Regulatory Authority to respond without delay to cases of non-compliance or violations. For cases that require immediate attention (*i.e.*, situations of actual or imminent accidental release of regulated plant material), the head of monitoring team will notify Regulatory Authorities immediately by telephone and positively within 24 hours in writing. Regulatory Authorities will advise the monitoring team on the appropriate course of remedial action. Upon receipt of instructions from Regulatory Authorities, the same would be communicated both verbally and in writing within 24 hours to the Trial In-charge (or Facility In-charge) and the Permitted Party by the monitoring team leader.

5. Monitoring of a confined field trial does not replace other monitoring activities or assessments of agronomic performance, nor does it exempt the plant material from meeting other phytosanitary and quality requirements under the relevant laws and rules.

5.2 Documentation Inspection

A review of required compliance documentation may be scheduled as a separate activity, but in practice it is often combined with either a trial site assessment or a storage facility inspection. The purpose of this inspection is to verify whether 1) copies of any relevant standard operating procedures are available and current; 2) all required forms and reports have been completed; and 3) copies of any mandatory notifications (*e.g.*, planting information submission, harvest information submission, accidental release information) have been transmitted to the Permitted Party or Regulatory Authority, as appropriate. The monitoring team will interact with the Facility In-charge or Trial In-charge in addition to perusal and inspection of the records. Compliance documentation that should be available for review may include:

1. Letter of permit authorizing conduct of the confined field trial;

2. Transport documentation (Record of Transport) for shipments of regulated plant material to, and between, field trial sites and contained facilities;

3. Storage facility documentation (Record of Storage; Record of Storage Inspection);
4. Current season documentation (Record of Planting; Record of Spatial Isolation and/or records for other methods of reproductive isolation);
5. Trial harvest and/or termination documentation (Record of Harvest/Termination and Disposition);
6. Post-harvest management documentation (Record of Post-Harvest Inspection); and
7. Any records related to compliance or corrective actions (Record of Corrective Action).

5.3 Storage Facility Inspection

Regulated plant material may be stored either at the trial site (*e.g.*, before planting or after harvest) or at fixed facilities, such as laboratories or greenhouses. In either case, the inspection should verify that storage facilities meet the minimum physical requirements stipulated in any applicable regulations, guidelines or SOPs, and that material management and monitoring processes are in place and being followed. The inspection should confirm that the following requirements have been met:

1. Regulated plant material is appropriately labelled and stored separately from any conventional seed or plant material in a fully enclosed, lockable space (*e.g.*, boxes, almirahs, cabinets, closet etc);
2. Access to storage areas is limited to authorized personnel and there must be evidence of some active access control system;
3. Areas or units designated for storage of regulated plant material must be cleaned prior to, and immediately following, the period of storage, and there should be records documenting these activities;
4. The storage area is clearly marked as containing regulated plant material, and used exclusively for that purpose;
5. All regulated plant material in storage is recorded on an inventory record, which also records all additions to, or removals from storage; and
6. Storage facilities be checked regularly to ensure they are secure, free of any waste or debris, and that material packaging or labelling has not been compromised, and this activity should be documented on records of storage inspection completed at least once every four weeks.

5.4 Field Trial Site Inspections

While monitoring of the trial site may occur at any time, the most useful times from a risk management perspective may include:

- **Prior to authorization –** to verify the physical surroundings and whether there are any circumstances that may be of special concern (*e.g.*, proximity of protected habitats and/or endangered species, proximity of cultivated fields of the same plant species; ownership and/or control of the trial site and surrounding isolation area);
- **During planting –** to verify material management procedures, cleaning of any equipment or implements used for planting, and disposition (*e.g.*, destruction or transport back to storage facility) of any remaining plant material;
- **During the period of crop flowering and prior to seed set –** this is the most critical time to verify if a method of reproductive isolation has been properly implemented, if appropriate monitoring activities are being carried out and documented, and if there are any conditions likely to result in a breach of reproductive isolation;
- **During harvest or trial termination –** to verify cleaning of any equipment or implements used for harvest or trial termination, the disposition of any harvested materials, and the destruction of any residual plant

material remaining on the trial site (*e.g.*, burning, chemical treatment, deep burial, soil incorporation); and

- **During the post-harvest period –** to verify if the area under postharvest restrictions is free of prohibited plants and if appropriate monitoring activities are being performed and documented.

  Specific considerations for monitoring teams conducted during different phases of confined field trial performance are briefly discussed below.

5.4.1 Site Location

- All four corners of each trial site must be clearly marked with physical landmarks suitable to permit identification of the trial site during both the current growing season and during any period of mandated post-harvest land use restriction.
- Confirm that the physical location of the trial site is actually the site identified on the map.

5.4.2 Reproductive Isolation

Regulated genetically engineered plants in the confined field trial must be reproductively isolated from any neighbouring sexually compatible plants by the isolation method described in the trial protocol and stipulated under the terms and conditions of authorization. A single field trial **site** must be reproductively isolated in its entirety by no less than one continuous method of reproductive isolation.

Spatial Isolation:

Spatial isolation is the standard method used for ensuring reproductive isolation of plants in the confined field trial. All plants in the trial (*e.g.*, regulated genetically engineered plants and any non-regulated plants used as checks or controls or in border rows) must be separated from other related species by the minimum isolation distance established by RCGM and indicated in the terms and conditions of authorization. Site inspections should confirm the following requirements related to spatial isolation:

- The spatial isolation distance must be of the required *distance* for the plant species undergoing trial, and it must be continuous and completely enclose the confined trial;
- The spatial isolation distance should be free of any prohibited plants. If prohibited plants are present, they must be removed prior to flowering otherwise this will be treated as a breach of reproductive isolation; and
- Records of monitoring of the spatial isolation distance should be available for review by the monitoring teams. These records should confirm that monitoring for prohibited plants within the isolation distance was performed at the required intervals and they should detail the occurrence and disposition (destruction by approved methods) of any prohibited plants found during routine monitoring.

5.4.3 Termination, Harvest and Disposition

At the termination of the confined field trial, either at harvest or for any reason prior to harvest, site visits should confirm that the following requirements have been met:

- All equipment and tools used to harvest the trial site must be cleaned and free of plant material before entering the trial site;
- Following harvest, all equipment and tools used must be cleaned on the trial site prior to removal in order to eliminate the unintended transport of regulated 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;
- All plant material harvested from a trial site and retained for future use must be transported from the trial site in approved, appropriately labelled containers, and in accordance with the SOP for the Transport of Regulated Genetically Engineered Plant Material. No harvested material may be retained without prior authorization by the Regulatory Authority; and,

- Records of harvest/termination should be available for review by the monitoring team. These records should detail the disposition of all harvested plant material, the cleaning of all equipment and tools used during harvest/termination, and the destruction (by approved methods) of all residual plant material on the trial site including any plant material from border rows.

5.4.4 Post-Harvest Period

All confined field trial sites are subject to a mandatory period of post-harvest land use restriction and the duration of this period is crop-specific and determined by the RCGM/GEAC, and stipulated in the terms and conditions of authorization. Site inspections during the post-harvest period should confirm that the following requirements have been met:

- The monitoring team should confirm whether post-harvest land use restrictions apply only to the trial site proper, or if they also include the spatial isolation distance (as would be the case in the event of a breach of reproductive isolation during the prior growing season).
- The field trial site should be marked according to the trial protocol. The four corners of each trial site must be maintained with physical landmarks suitable to permit identification of the trial site during the mandated period of post-harvest land use restriction (*e.g.* fence post, PVC piping).
- During the entire post-harvest period, the land under post-harvest restrictions must be maintained free of prohibited plants. If prohibited plants are present, they must be removed prior to flowering.
- Records of monitoring of the post-harvest area should be available for review by the monitoring teams. These records should confirm that monitoring for prohibited plants within the post-harvest area was performed at the required intervals and they should detail the occurrence and disposition (destruction by approved methods) of any prohibited plants found during routine monitoring.

5.5 Completing The Monitoring Report

Upon completion of the facility and/or site visit, the monitoring team should have a closing meeting with the Permitted Party, Trial In-charge and/or Facility In-charge (as appropriate) to present the findings and conclusions so they are understood and acknowledged by the Permitted Party, Trial In-charge and/or Facility In-charge, and to agree, if appropriate, on any corrective actions that may be necessary to bring the confined field trial into full compliance. Minutes of the meeting, including records of attendance, should be noted in the monitoring report. Any differences of opinion regarding the inspection findings and/or conclusions between the monitoring teams and the Trial In-charge should be discussed and if possible resolved. If these are irresolvable, the divergent opinions should be recorded.

The monitoring team should complete the monitoring report and send copies of this report to the Regulatory Authority, the monitoring body (*e.g.*, MEC, SBCC, DLC) and the Permitted Party.

In the event of any compliance infraction discovered during the monitoring process that has resulted in an accidental release of regulated plant material, the monitoring team will notify Regulatory Authorities immediately by telephone and positively within 24 hours in writing. Regulatory Authorities will advise the monitoring team on the appropriate course of remedial action. Upon receipt of instructions from Regulatory Authorities, the same would be communicated both verbally and in writing within 24 hours to the Permitted Party, Trial In-charge or Facility In-charge by the monitoring team leader. A Record of Corrective Action, detailing the incident and the corrective action taken, is to be initiated by the Permitted Party, Trial In-charge or Facility In-charge. In the event of any nonconformities requiring immediate corrective action, the monitoring team leader should arrange a time for a follow-up site visit to confirm that the necessary actions have been implemented.

6 PROFORMA CONFINED FIELD TRIAL INSPECTION REPORT

INSTRUCTIONS

Parts A - H of this report should be completed for each site location. Additional copies of Part B of this form can be completed in cases where there is more than a single confined field trial site at a given trial site location.

A copy of this completed report should be submitted to the **Regulatory Authority** (RCGM/GEAC), the relevant monitoring body (MEC, SBCC, DLC), and the Permitted Party **WITHIN FIVE (5) DAYS** of the site visit.

In the event of any **compliance infraction** discovered during a site visit that results in an accidental release of regulated genetically engineered plant material, Regulatory Authorities will be notified immediately by telephone and in writing within 24 hours. Regulatory Authorities will advise on the necessary corrective actions to be implemented and a **Record of Corrective Action**, detailing the incident and the corrective action taken, is to be initiated by the Permitted Part, Trial In-Charge or Facility In-Charge and provided to the Monitoring Team. Upon completion of the corrective action, copies of the **Record of Corrective Action** will be forwarded to the **Regulatory Authority** and the Permitted Party.

PART A: GENERAL INFORMATION PERMITTED PARTY		
Last Name	First Name	MI
Company/Organization	Contact	
Telephone	Facsimile	Electronic Mail
Address		

TRIAL IN-CHARGE OR FACILITY IN-CHARGE		
Last Name	First Name	MI
Company/Organization	Contact	
Telephone	Facsimile	Electronic Mail
Address		

PART B: TRIAL SITE INFORMATION

Legal or Descriptive Land Location of Trial Site			
Crop Planted at Trial Site ☐ Cotton ☐ BrinjaL ☐ Other (list) Date of sowing _____			
Timing of the Inspection and Stage of Crop Development ☐ At planting ☐ Vegetative, pre-flowering ☐ Flowering ☐ After flowering ☐ At harvest ☐ Post-harvest Copies of inspection reports at various stages be made available to monitoring teams for all subsequent inspections.			
1.	Are physical landmarks (PVC piping, fence post, etc.) at located each corner of the trial site?	☐ Yes	☐ No
2.	Do measurements of the trial size match information on the trial site map?	☐ Yes	☐ No
3.	Distance to the nearest cultivated fields of the same plant speciesas the plants in the confined field trial:	_____ Meters	
4.	Distance to the nearest cultivated crop of any kind:	_____ Meters	
5.	Is the trial site, including the spatial isolation distance, under the control of the Trial In-Charge and/or Permitted Party?	☐ Yes	☐ No
6.	Is there 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?	☐ Yes	☐ No
7.	Is there a bound log book including the name, address and affiliation of all personnel who have entered the trial site?	☐ Yes	☐ No
8.	Was planting/harvesting equipment/implements cleaned in the appropriate manner prior to, and after, use on the trial site?	☐ Yes	☐ No
9.	Event(s) planted at the trial site (attach list if necessary)		

PART C: REPRODUCTIVE ISOLATION

Method of Reproductive Isolation ☐ Spatial Isolation ☐ Other (list)				
1.	Do measurements confirm that the trial site has the appropriate isolation distance? (cotton: 50 m; brinjal: 300 m; etc)	☐ Yes	☐ No	
2.	Is the isolation distance free of any **prohibited plants**? (*e.g.*, plants of any species sexually compatible with the regulated plants)	☐ Yes	☐ No	
3.	Is there a written **Record of Spatial Isolation**?	☐ Yes	☐ No	
4.	Does the Record of Spatial Isolation confirm that monitoring of the isolation distance has been performed at the required intervals? (see Letter of Permit from Regulatory Authority)	☐ Yes	☐ No	
5.	Were growth stages of the trial plants, including any prohibited plants observed in the isolation distance, recorded?	☐ Yes	☐ No	
6.	If records indicate that prohibited plants have been removed from the isolation distance during routine monitoring, do they also indicate themethod of destruction, and was this appropriate?	☐ Yes	☐ No	☐ NA
7.	Have there been any prior instances of non-compliance during the current growing season?	☐ Yes	☐ No	
8.	If the answer to C.7 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No	☐ NA

PART D: STORAGE OF REGULATED PLANT MATERIAL

ONLY COMPLETE IF REGULATED PLANT MATERIAL IS IN STORAGE AT THIS LOCATION ☐ Regulated plant material is stored at this location				
1.	Is the regulated plant material stored separately from conventional seeds in a fully enclosed, lockable space? (*e.g.*, boxes, almirahs, cabinets, closet etc)	☐ Yes	☐ No	
2.	Is the storage area clearly labelled as containing regulated plant material and is it used exclusively for that purpose?	☐ Yes	☐ No	
3.	If multiple regulated articles are in storage, are they within separate, sealed containers?	☐ Yes	☐ No	
4.	Is the storage area clean and free of any waste or debris?	☐ Yes	☐ No	
5.	Is there a **Record of Inventory** that details all of the regulated plant material in storage and any additions to, or removals from, storage?	☐ Yes	☐ No	
6.	Based on a sampling of entries from the **Record of Inventory**, is there a correlation between the physical presence of an inventory item andthe **Record of Inventory**?	☐ Yes	☐ No	
7.	Is there a **Record of Storage Inspection**?	☐ Yes	☐ No	
8.	If it exists, does the **Record of Storage Inspection** confirm that the storage location has been inspected at least once per month?	☐ Yes	☐ No	
9.	Have there been any prior instances of non-compliance during the current year?	☐ Yes	☐ No	
10.	If the answer to D.9 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No	☐ NA

PART E: POST-HARVEST RESTRICTIONS

ONLY COMPLETE IF THIS IS A PRIOR-YEAR TRIAL SITE UNDER POST-HARVEST RESTRICTIONS

☐ Prior-year trial site(s) under post-harvest land use restrictions at this location

1.	Is the post-harvest trial site clearly marked with physical landmarks at each corner?	☐ Yes	☐ No	
2.	Does the post-harvest area under restriction include only the trial site proper? (If not, it also includes the spatial isolation distance)	☐ Yes	☐ No	
3.	Does the Trial In-charge (or Permitted Party) have control of the entire area under post-harvest land use restrictions?	☐ Yes	☐ No	
4.	Is the post-harvest trial site being managed in a way that enables the identification of volunteers, or other prohibited plants, and theirdestruction?	☐ Yes	☐ No	
5.	Is there a **Record of Post-Harvest Monitoring**?	☐ Yes	☐ No	
6.	If it exists, does the **Record of Post-Harvest Monitoring** confirm that the post-harvest trial site has been monitored at least once every four weeks for the presence of prohibited plants?	☐ Yes	☐ No	
7.	If records indicate that prohibited plants have been removed from the post-harvest site during routine monitoring, do they also indicate themethod of destruction, and was this appropriate?	☐ Yes	☐ No	☐ NA
8.	Have there been any prior instances of non-compliance during the current post-harvest period?	☐ Yes	☐ No	
9.	If the answer to E.8 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No	☐ NA

PART F: DOCUMENTATION AND RECORD KEEPING

1.	Are copies of SOPs and related records readily accessible and up-to-date for this trial site location?	☐ Yes	☐ No
2.	Is a copy of the letter of permit for all events planted at this trial location readily accessible?	☐ Yes	☐ No
3.	Are the **Record of Transport** documents complete?	☐ Yes	☐ No
4.	Has a **Record of Planting** and a trial site map been completed?	☐ Yes	☐ No
5.	Have the **Record of Planting** and trial site map been forwarded to the **Regulatory Authority**?	☐ Yes	☐ No

PART G: ADDITIONAL COMMENTS

Summarize :-

- any discussions with the Trial In-charge or other Personnel,

- feedback on the SOPs maintened

- any recommended corrective actions and

- any other pertinent details/ observations.

PART H: COMPLIANCE ASSESSMENT

PLEASE INDICATE ONE OF THE FOLLOWING CATEGORIES OF INSPECTION STATUS

☐ **No compliance deviations, all documentation in order.**

Field trial conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants and the Compliance Documentation was up-to-date.

- No actions required

☐ **No compliance deviations, but with documentation deficiencies.**

Field trial conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants, **BUT the Compliance Documentation was not up-to-date**.

- Instruct the Trial In-charge on actions needed to update the Compliance Documentation or other records
- Make a note to verify any corrective actions during the next site inspection

☐ **Compliance deviations, but no documentation deficiencies.**

Field trial **NOT conducted in accordance with SOPs** for Confined Field Trials of Regulated Genetically Engineered Plants BUT the Compliance Documentation was up-to-date.· Request a

- **Record of Corrective Action** be initiated and consult with the Trial In-charge on the appropriate corrective actions to be taken. In the event of any accidental release, notify the **Regulatory Authority** immediately by telephone and in writing within 24 hours.
- Schedule a follow-up inspection as soon as practical to verify that appropriate corrective actions have been implemented.
- If the nature of the infraction is such that destruction of the trial site is warranted, consult with the **Regulatory Authority** prior to instigating this action

☐ **Compliance deviations AND documentation deficiencies.**

Field trial **NOT conducted in accordance with SOPs** for Confined Field Trials of Regulated Genetically Engineered Plants **AND the Compliance Documentation was not up-to-date**.

- Request a **Record of Corrective Action** be initiated and consult with the Trial In-charge on the appropriate corrective actions to be taken. In the event of any accidental release, notify the **Regulatory Authority** immediately by telephone and in writing within 24 hours.
- Instruct the Trial In-charge on actions needed to update the Compliance Documentation or other records.
- Schedule a follow-up inspection as soon as practical to verify that appropriate corrective actions have been implemented.
- If the nature of the infraction is such that destruction of the trial site is warranted, consult with the **Regulatory Authority** prior to instigating this action

PART I: Monitoring Team VERIFICATION

This activity has been carried out to assess compliance with the Guidelines for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India and related Standard Operating Procedures. By my signature, below, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

Names and Designation of Monitoring Team — Signature and date

LEADER : _____

Members : 1. _____

2. _____

3. _____

4. _____

5. _____