MONITORING MANUAL

Monitoring Confined Field Trials of Regulated Genetically Engineered (GE) Plants

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Center for Environmental Risk Assessment

PHASE-II Capacity Building Project on Biosafety

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

Government of India

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Monitoring Confined Field Trials of Regulated, Genetically Engineered (GE) Plants: Monitoring Manual

Prepared by
Ministry of Environment, Forest and Climate Change (MoEF&CC)
in association with Centre for Environmental Risk Assessment,ILSI Research Foundation (CERA-ILSI)under UNEP/GEF supported Phase-II Capacity Building Project on Biosafety

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Message

I am pleased to introduce the Manual on Monitoring Confined Field Trials of Regulated Genetically Engineered (GE) Plants.

The manual has been developed as part of the ongoing UNEP-GEF supported Phase-II Capacity Building Project on Biosafety being implemented by the Ministry of Environment, Forest and Climate Change and aims to serve as a resource document for all those involved in the development and regulation of GE plants.

This is an extremely important initiative as India is an emerging developer of GE plants, having a significant agriculture research base, both in the Public and Private institutions. Effective monitoring of confined field trials or regulated GE plants is extremely important in view of the unique nature of the GE plant.

It is also the stage during which the plant variety expressing new traits are for the first time introduced into the environment in controlled conditions. This calls for appropriate confinement measures such as reproductive isolation measures, post-harvest restrictions and institutional mechanisms for timely monitoring to ensure regulatory compliance.

I congratulate all those who were involved in preparing this manual.

I am confident that this initiative will help in addressing some of the

challenges related to GM crop regulations and also improve the public perception on these issues.

(Prakash Javadekar)

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PREFACE

Agriculture is a way of life for more than sixty per cent of India's population. The productive agricultural areas are encountering serious problems of sub-soil water depletion, deficiency of micronutrients in the soil and increase in the use of pesticides, fungicides and herbicides to control pests, pathogens and persistent weeds. Human intervention for the improvement of crops, trees, livestock and fish is nothing new. With the limited amount of land available to agriculture, modern biotechnologies could complement and improve the efficiency of traditional selection and breeding techniques to enhance agricultural productivity.

Genetic engineering in agriculture is a relatively new field, and much about the interaction of Genetically Modified Organisms (GMOs) with various ecosystems is not yet known. Some of the concerns about the new technology include its potential adverse effects on biological diversity including agro-biodiversity and potential risks to human health and therefore public concerns on the safety of genetically modified crops is understandable. Because of the perceived risks, Public debate on confined field trials is embroiled in controversy over the adequacy of the safety measures imposed by the regulatory agencies as well as its compliance.

Management and monitoring of GM crop field trials is an important step in the regulatory process as it provides unique information on the behaviour of the new plant variety in different ecosystems. I am happy to inform that as part of the ongoing Phase II Capacity Building

Contd...

Project on Biosafety, the Ministry of Environment, Forest and Climate Change (MoEF&CC) has prepared the "Manual on Monitoring Confined Field Trials of Regulated Genetically Engineered Plants" with a view to strengthen the capacity of researchers, developers and regulators in conducting the field trials with GM crops in a scientific manner.

This manual covers three broad topics: (1) risk assessment and management of confined field trials, (2) the Indian guidelines for the management of confined field trials, and (3) the monitors' role in the management of risks from confined field trials. The training tool is aimed to create a pool of resource personnel to assist the regulatory agencies in monitoring the field trials.

The manual explains in detail the best monitoring practices to be followed at every stage of conducting field trials including the scientific basis for confinement, process of monitoring and assessing risks and suggestions for corrective measures for managing the risks.

The document has been prepared through a consultative approach and comments received from several organisations and experts have been extremely useful in validating this document. I express my deep appreciation for the sincere and dedicated efforts put in by Dr Ranjini Warrier, Adviser, MoEF&CC and would also like to acknowledge the assistance provided by Dr Morven Mclean, Executive Director, CERAILSI and her team in developing this manual.

I am confident that this manual would go a long way in enhancing awareness on conduct of GM crop field trials and help in creating a pool of trained resource persons.

Hem Pande

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Introduction

1.1 Introduction to Confined Field Trials (CFTs)

Before new genetically engineered (GE) plant varieties can be grown as commercial crops, researchers must test these plants in outdoor field trials to fully evaluate their agronomic utility and environmental impacts. Confined field trials[1] (CFTs) are small-scale experimental trials of GE plant varieties, maintained under carefully controlled conditions, undertaken for the purpose of evaluating plants before their introduction into agriculture. They represent a greater degree of environmental exposure than work performed in contained facilities, such as laboratories, growth chambers and greenhouses, where a physical structure ensures safety, but a much smaller degree of exposure than the unconfined commercial planting of approved GE crop varieties. CFTs have been adopted by biotechnology regulatory authorities throughout the world as an essential research process for enabling the biosafety evaluation of experimental GE plants.

When a developer undertakes the first CFTs of a newly developed GE plant, the potential environmental impacts of the plant may not be fully understood, and this requires regulatory oversight and environmental risk management. To ensure that CFTs are conducted with no significant risks to human health and the environment regulatory authorities should issue clear field trial management guidelines, the field Trial In-charge should carefully follow the guidelines, and field trials should be monitored to verify that the trial is in compliance with all applicable laws and regulations. Therefore, the oversight of CFTs by properly trained monitors is an essential part of the CFT regulatory process.

Since the first trials were carried out in Canada and the U.S. in 1987, tens of thousands of CFTs have been conducted safely in various countries around the world. The safe conduct of CFTs can only be accomplished through the combination of a robust regulatory framework, science-based risk mitigation measures, trained field personnel dedicated to abiding by the terms and conditions of trial authorization, and a trained and vigilant monitoring staff. Weaknesses in any of these areas undermine public trust in the regulatory framework. Public opinion research has demonstrated that public acceptance of new technologies, including biotechnology, is largely dependent on confidence in regulatory systems that oversee the technology. Poor management of CFTs not only impacts the reputations of the researchers themselves, but can also reflect negatively on the entire research and development community, the regulatory process and the technology.

Contained Use
Laboratory or Green house experiments

Confined Use
Small-scale isolated Experimental field trials

Unconfined Use
Farm-scale evaluations Farmers fields

Figure 1: The development of a new GE crop involves contained use, in growth chambers and greenhouses, confined field trials, and large-scale field evaluations.

[1] Terms in italic boldface are defined in the Glossary, Appendix II.

1.2 Purposes of CFTs

CFTs serve multiple purposes. For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel plant/trait combinations in an open environment. In this regard, CFTs serve the same purpose as conventional breeding trials. CFTs are also necessary to collect the agronomic and ecological data required to complete any environmental safety assessment of a GE plant.

What Is a Confined Field Trial ?

A confined field trial is a field experiment of growing a regulated, GE plant in the environment under specific terms and conditions that are intended to mitigate the establishment and spread of the plant. Embodied in this definition are three important considerations.

1. CFTs are of limited size, typically carried out on a small scale.
2. CFTs are experimental activities conducted to collect data, including data regarding potential biosafety impacts.
3. CFTs are conducted under conditions of reproductive and physical isolation known to mitigate the dissemination of the experimental plant, its persistence in the environment, and its introduction into human food or livestock feed.

The types of studies include

- Assessment of morphological characteristics that could signal any increased tendency to weediness, for example, any changes in seed dissemination; seed dormancy; time-to-germination or germination rates; time-to-maturity; disease and/or pest resistance; or abiotic stress tolerance.
- Evaluation of the environmental fate of novel plant-expressed proteins, particularly pest control proteins. This can provide important estimates of environmental exposure in both soil and water, and persistence within the environment.
- Assessment of the potential impacts of insect-resistant plants on non-target, beneficial and endangered insects. These studies can be used to compare the impacts from conventional forms of insect control with the new GE technology.

In addition, CFTs provide plant tissues for other regulatory studies. For example, as part of the core characterization of a GE plant, it is necessary to measure the levels of protein expression from any newly introduced genes, in a variety of plant tissues, over the course of plant development. These measurements are generally performed on tissues derived from field-grown plants, and the data are used to predict levels of exposure to novel dietary proteins for humans or livestock animals consuming the edible portions of the GE plant or derived plant products. In addition, CFTs permit the production of sufficient quantities of plant material to conduct nutrient compositional analyses and, when necessary, for use in livestock feeding trials.

From a policy standpoint, the implementation, monitoring, and enforcement of effective risk management strategies for CFTs help regulatory authorities to build public confidence in the biosafety regulatory system. Lastly, CFTs provide an opportunity for farmers to appreciate the potential benefits to be derived from the cultivation of these new crops and to understand any impacts that may result.

2

Regulation of CFTs

2.1 Regulatory Approaches to CFTs

Many countries have developed new regulatory regimes or amended existing regulations to assess the safety of GE plants and ensure that the introduction of these products into agriculture and food production systems will not result in adverse environmental and human health consequences. A "process trigger" is used in the Cartagena Protocol on Biosafety and in virtually all countries that have developed regulatory systems for GE plants and foods derived from them. That is, the process of creating a new plant by genetic engineering triggers the need for regulation.

From the experiences of those developed nations with established regulatory systems, there is no consensus on a single best regulatory approach. Some biotechnology regulatory systems were developed de novo as a comprehensive plan designed from the outset to anticipate every contingency and to be integrated and coherent, both internally and with other national policies. Many other regulatory systems were developed in piecemeal fashion, usually beginning with voluntary guidelines and standards developed cooperatively by academia, industry, and government. These documents eventually evolved into statutory instruments either under existing legislation covering food and agricultural products, or under new legislation dealing specifically with gene technology.

2.2 Regulatory Framework in India

In India, the manufacture, import, research, and release of genetically modified organisms (GMOs), as well as products made by the use of such organisms, are governed by the rules notified by the Ministry of Environment, Forest and Climate Change (MoEF&CC), on December 5, 1989, under the Environment (Protection) Act 1986[2]. The Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells[3] commonly referred to as "Rules 1989," cover the areas of research, including CFTs, as well as large-scale applications of genetically engineered organisms (GEOs) and products made from GEOs, throughout India. The regulatory agencies responsible for implementation of the Rules 1989 are MoEF&CC, the Department

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (http://bch.cbd.int/protocol/background/) is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003. The Protocol applies to the transboundary movement of LMOs that will be intentionally introduced into the environment by the country of import. Because CFTs are maintained to prevent the introduction of GE plants into the environment during the development process, the management of CFTs is not governed by the Protocol.

[2] http://envfor.nic.in/legis/env/env1.html, [3] http://envfor.nic.in/legis/hsm/hsm3.html

of Biotechnology (DBT) and state governments, through six competent authorities:

- Recombinant DNA Advisory Committee (RDAC)
- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Approval Committee (GEAC)
- Institutional Biosafety Committees (IBSC)
- State Biotechnology Coordination Committees (SBCCs)
- District Level Committees (DLCs)

While the RDAC is advisory in function, the IBSC, RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes. The composition of each committee is defined in the Rules, 1989.

In India, the conduct of CFTs is subject to government regulation, from the initial application process through any post-harvest management of the field trial site. To verify that CFTs are conducted in compliance with the regulations, various mechanisms have been put in place from time to time. Presently, CFTs are monitored by the Central Compliance Committees (CCCs) set up by RCGM/GEAC specifically for various trials. The CCCs consists of subject specific experts, representatives from RCGM/GEAC, representative from state agriculture department and state agricultural universities. The inspections by CCCs can be conducted at the time of planting, during the growing and harvesting season, and during the period of post-harvest land use restrictions. Monitoring agencies also have the authority to inspect contained facilities that may be used for the storage of regulated genetically engineered plant material.

2.3 Types of CFTs

The types of CFTs generally undertaken during the development of GE plants are as follows:

I. **Event Selection Trials:** During the course of product development it is common and desirable to undertake event selection in the field under confined conditions. Typically, this includes planting small plots comprising several to dozens of events of the same plant species so that a preliminary phenotypic evaluation can be completed to facilitate the selection of one to a few events for further evaluation. Such trials (also referred to as strip trials) are permitted as Event Selection trials by RCGM.

ii. **Biosafety Research Level–I Trials (BRL-I):** RCGM, functioning in the DBT, is the Regulatory Authority for BRL-I trials. These trials are limited in size to no more than 1 acre (0.4 ha) per trial site location and a maximum cumulative total of 20 acres (8.1 ha) for all locations for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.

iii. **Biosafety Research Level–II Trials (BRL-II):** GEAC, functioning in the MoEF&CC, is the Regulatory Authority for BRL-II trials. These are limited in size to no more than 2.5 acres (1 ha) per trial site location and number of locations to be decided on a case by case basis for each plant species/construct combination (e.g., one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.

An application to GEAC for the environmental release of a new event will not be considered unless the Applicant has completed:

1. First crop season of CFTs at the level of Biosafety Research Level I to be followed by;
2. Second crop season of CFTs at the level of Biosafety Research Level I or Biosafety Research Level II.
3. Third crop season of CFTs at the level of Biosafety Research Level II.

iv. **Experimental Seed Production:** Production of seeds for the selected events is undertaken under confined field trial conditions for the next phase of trials by the applicants and is permitted by RCGM and GEAC, based on the size of the trial.

v. **Production of plant material for food and feed safety studies:** Developers have to gene-rate plant material for undertaking various food and feed safety studies such as toxicity and feeding studies and the same has to be undertaken under confined field trial conditions. The permission for trials for production of plant material is given by RCGM and GEAC, based on the size of the trial.

vi. **Other environmental safety studies:** During the course of data generation for regulatory approvals, sometimes the developers have to undertake trait or crop specific studies under confined field conditions for generating data on environmental safety. These are in addition to BRL-I and BRL-II trials and are targeted at generating specific information using specific experimental designs e.g. residue analysis, crossability studies etc. Such CFTs are permitted by RCGM and GEAC based on size of the trial.

The final authority for approval of all CFTs is GEAC.

2.4 Application Process

The assessment of an application for a CFT begins at the institution of the Permitted Party who wishes to conduct the CFT. An "Application for Confined Field Trial" is made to the IBSC for permission to conduct a confined field trial. The application form collects all of the key pieces of information needed to evaluate any environmental risks posed by the field trial:

- Identification of the applicant and the Trial In-charge
- Description of the unmodified plant species
- Description of the genetically engineered plant
- Location and description of the trial site, including a detailed map
- Description of the experimental protocols and trial management, including emergency management for accidental releases
- Description of how the GE plant material will be transported and stored

The application must provide the risk assessors with a full understanding of the biology of the unmodified plant, especially in regard to the plant's reproductive biology. In Chapters 4 & 7, it will be seen how a plant's reproductive biology determines which confinement measures will be most effective.

The IBSC evaluates the application, and if the application is approved, the IBSC will recommend that the applicant submit the application to the RCGM or GEAC depending on the size of the proposed trials.

3

Assessment and Management of Risks Posed by CFTs

3.1 Risk Assessment

Risk assessment is a science-driven process that includes identifying hazards, assessing their magnitude and duration, and estimating their likelihood of occurrence. In the context of genetically engineered plants, environmental risk can be defined as the probability that some valued environmental resource (including human and animal health) will be adversely affected by exposure to a hazard caused by the GE plant. As it is commonly expressed, risk is a function of the nature and severity of the hazard as well as the extent to which the environmental resource will be exposed to the hazard.

Risk = ¦ (hazard x exposure)

To evaluate the hazard portion of the equation, a risk assessor first identifies the types of adverse effects that the GE plant may cause to the valued environmental resource (e.g., harm to an endangered species or to water quality). Each potential hazard is then characterized in terms of its severity in quantitative (e.g., dose/response relationship) or qualitative terms. The potential environmental consequences are examined in terms of their severity, as well as their spatial and temporal extent. In other words, the risk assessor first considers all the possible hazards and their causal links and pathways, and then identifies hazards that are sufficiently severe to cause significant harm to the environment.

Equally important is the exposure portion of the equation which represents the mechanisms by which the environment may be exposed to a hazard caused by the GE plant. This includes an estimation of the frequency and intensity of the exposure, taking into account whether the environmental resource can move and whether the GE plant could spread to new areas. In the final step in the risk assessment, the information regarding hazard and exposure are integrated to characterize the risk associated with the proposed activity. For example, a crop that has been genetically engineered to be drought tolerant could be more competitive than native plants—when drought conditions persist for a long period of time—thereby posing a hazard of displacing native plants in the environment. If the crop is widely grown, its exposure to native plants might be increased. The risk assessment process would evaluate the nature of any competitiveness and thereby assess the severity of the hazard. At the same time the assessment would determine how frequently and to what extent native plant populations would be exposed to the crop.

Risk characterization can be represented as a matrix where the separate characterizations of hazard and exposure interact[4]. Risks can be deemed minimal if the hazard is of low magnitude, or if the environmental exposure to the hazard is low, based on the evidence available. In other words, minimal risk situations occur when either the hazard is minor, or the amount of exposure is very small, or both.

		Risk Characterization			
Exposure	Highly Unlikely	Negligible	Negligible	Low	Moderate
	Unlikely	Negligible	Low	Moderate	High
	Likely	Negligible	Low	High	High
	Highly Likely	Low	Moderate	High	High
		Marginal	Minor	Intermediate	Major
		hazard			

Figure 2: This matrix demonstrates the relationship between Hazard and Exposure in the characterization of risk.

[4] OGTR (2005) Risk Analysis Framework. Australian Government, Department of Health and Aging. Office of the Gene Technology Regulator. www.ogtr.gov.au

3.2 Risk Assessment in the Context of CFTs

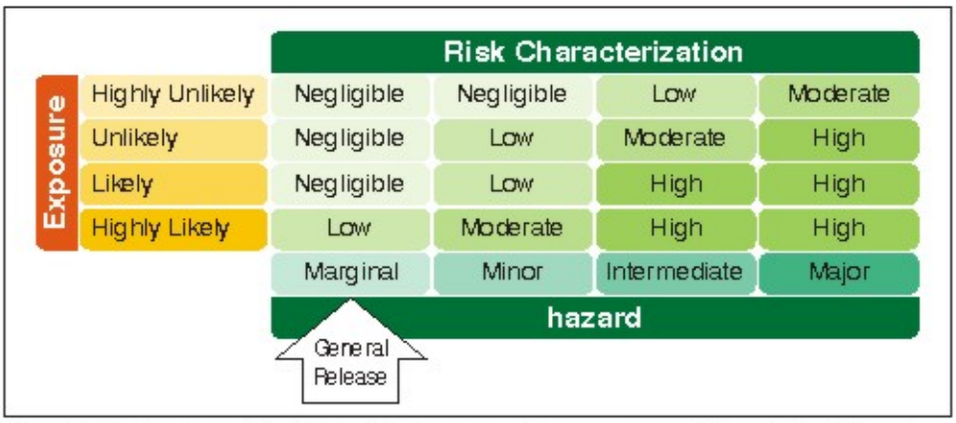
It is important to point out that risks from CFTs and risks from unconfined releases are assessed and managed differently. For an unconfined (general) release, there is little or no possibility of controlling the exposure component of risk because the intention is to introduce the GE plant widely into commercial agriculture, with few or no provisions to limit the geographic distribution of the plant. Therefore, the focus must be on rigorous risk assess-ment, and regulators must be satisfied that potential hazards are not significant, to minimize risk both to the environment and to people and animals.

Conversely, for a CFT, where the potential hazards may not be fully understood without data collected during the trial, the focus must be on minimizing environmental exposure. In India it is the responsibility of the GEAC and RCGM to perform a case-by-case assessment of any risks associated with each proposed CFT. To ensure that the trial will be conducted with minimal environmental risk, terms and conditions are imposed by the regulators (for example, limiting the size of the CFT and imposing reproductive isolation measures). These measures are based on the biology of the non-GE plant and the phenotype of the GE version.

Going back to the risk equation presented at the beginning of this chapter, risk from commercial releases of GE plants is reduced by ensuring that the environmental hazard is insignificant. On the other hand, risk from CFTs is reduced by ensuring that the environmental exposure is insignificant. Because of this fundamental difference in the management of risks, an application for the commercial release of GE crop will tend to have much more information than an application for a CFT, including, for example, a full genetic and molecular characterization of the plant. This additional information is to enable risk assessors to determine that there are no significant hazards associated with the widespread use of a GE crop in commercial agriculture.

In essence, CFTs using GE plants are managed so that the regulated plant cannot escape the field trial site or persist in the environment. At the end of the field trial, the plant and any residual plant material is either removed or destroyed, so that it cannot impact the environment.

It is important for monitors to remember that, in India and most other countries, the regulators perform a risk assessment, appropriate to the context of CFT, prior to any decision making regarding the authorization of a particular confined field trial. In other words, the risk assessment process is completely separate from and precedes, the monitoring function.



In the management of risks from CFTs, the goal is to minimize any environmental exposure.

Figure 3: The risk characterization matrix shows how risks are managed differently for CFTs and commercial/general releases.

4

Risk Management Methods for CFTs

4.1 Permit Conditions

Potential risks from a particular CFT are assessed before the trial is authorized by regulators, but as mentioned in Chapter 1, GE plants that will be grown in CFTs may not be fully characterized and may contain transgenes with which regulators have little experience. To deal with any residual uncertainties following the risk assessment, regulators typically impose a combination of standard and case-specific risk management conditions that the Permitted Party must follow throughout the course of the trial.

From a regulatory standpoint, the terms and conditions governing the conduct of CFTs normally include specific provisions for each stage of the trial:

- Transportation to the CFT site
- Storage of regulated plant material
- Layout of the trial site
- Planting the GE crop and controls
- Crop management throughout the trial
- Harvesting the GE and control plant materials
- Disposition, transport, and storage of harvested plant material
- Post-harvest management of trial sites
- Reporting

Central to the identification of effective confinement conditions is a full understanding of the reproductive biology of the plant. When properly designed and implemented, these measures ensure that the confined field trial does not pose a threat to the environment or to humans or animals.

4.2 Reproductive Isolation

The CFT must be managed in a manner that prevents the dissemination of regulated plant material into the environment. This is accomplished by imposing conditions of reproductive isolation on all plants within the confined trial site. The goal of reproductive isolation in a CFT is to ensure that regulated GE plants do not pollinate sexually compatible plants, including cultivated plants or free-living plants of the same crop species, or any wild plants of a species sexually compatible with the crop. It is important; to remember that for pollen-mediated gene flow and introgression to occur, a number of conditions must be satisfied: the two plants must be sexually compatible, fecundity must coincide, a pollen vector must be available, and the progeny plants must be fertile and able to persist in the environment.

Monitoring Best Practice

The monitoring team should familiarize itself with the reproductive isolation methods that were imposed in the CFT permit approval letter, and the limitations of each method, before undertaking the inspection of the field trial. The monitoring team should also be aware of other reproductive isolation methods that were not imposed but might also be effective for the CFT they will be visiting.

In conducting the risk assessment for a confined field trial, one of the most important considerations is whether the method of genetic modification, or the trait introduced into the GE plant, is likely to have altered the basic reproductive biology of the unmodified plant species. If it has not, then the standard conditions known to be effective at reproductively isolating the conventional plant variety will also apply for the GE variety. Important considerations include:

- Whether the plant is self-pollinating or cross-pollinating
- Mechanisms for pollen dispersal (wind, insects, birds, etc.)
- Pollen viability
- Presence of nearby sexually compatible relatives

Reproductive isolation requires the implementation of one or more crop-specific measures that may include one or more of the following measures, discussed in detail in Chapter 7:

- Spatial and/or physical isolation from other sexually compatible plants
- Temporal isolation of pollination (i.e., planting earlier or later than any nearby sexually compatible plants)
- Removal of flowers
- Bagging of flowers/tassels to prevent open pollination
- Enclosing the GE plants in a tent
- Use of border rows of conventional plants of the same variety to act as pollen traps for insect-pollinated species
- Termination of the trial prior to flowering

- Cultivation practices of the crop (vegetative propagation vs. propagation through true seed)

4.3 Preventing Persistence in the Environment

CFTs must be conducted in such a manner that the regulated GE plant, or its offspring, will not persist in the environment. At the termination of the field trial, any viable plant material likely to give rise to volunteer plants in subsequent growing seasons should be destroyed, unless the Regulatory Authority has given express permission to retain this material for research purposes. To manage any volunteers (or progeny plants) that may arise, there should be a period of post-harvest land use restriction (i.e., no plan-ting of the same or a sexually compatible plant species), during which there is active monitoring for, and destruction of, any prohibited plants before flowering.

The period of post-harvest restriction depends on the plant species and particularly its seed dormancy characteristics. It may range from one growing season, in the case of maize or cotton, to 2–3 years for mustard (*Brassica juncea*).

Again, from the risk assessment perspective it is important to consider whether the genetic modification is likely to have altered any properties of seed dormancy. If it has not, then knowledge of the persistence of viable seed from the conventional variety in the soil can be used to determine the appropriate period of postharvest restriction and monitoring.

4.4 Preventing Introduction into the Food and Feed Pathways

This is perhaps the most critical control point in the proper management of CFTs. It is the area most prone to human error and represents the most likely pathway by which experimental GE plant material may "escape." At this stage, effective risk management requires:

- Controlling the movement of plant material onto and off the trial site
- Controlling the storage of seed and other plant material
- Controlling the disposal of residual or excess plant material on the trial site – for example, excess planting materials, material remaining after harvest, and material from rogueing, detasseling, or deflowering activities
- Controlling the disposition of any material retained after harvest, such as seed that is saved for subsequent analyses

Like quality assurance programs in other fields, this area of "material management" requires the implementation of effective and documented control processes which are backed up by monitoring and verification procedures.

5

Transportation and Storage of Regulated GE Plant Material

The Standard Operating Procedure for the Transport and Storage of Regulated Genetically Engineered Plant Materials describe the types of containers that must be used, how the containers must be labelled, and what records must be kept for any transported material. In addition, the Permitted Party should ensure, and the monitoring process should verify, that all personnel who may be involved in the shipment, receipt, and storage of regulated plant material, and those who may have access to material storage areas, are properly trained. This means that personnel should understand their responsibilities to properly handle, package, label, and store these materials, and to maintain appropriate records. They must also know what actions should be taken, and by whom, as well as the reporting requirements in the event of an accidental release.

5.1 Transport

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 bag, 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 that are proposed

to be re-used must be cleaned after use. Alternatively, primary and secondary containers must be destroyed using a method that devitalizes any plant material.

A.3.8. Any residual seed or propagable material recovered during the process of cleaning must be destroyed using a method that devitalizes any plant material.5

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 sent 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, unless the secondary container was damaged during transport. 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. A copy of the completed Record of Transport should be sent in writing (email or fax) by the Recipient

A.6.4. 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.6.5. If it is suspected that an accidental release has occurred, the corrective action requirements in Section A.7 must be followed.

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 plant material must either be retained, using appropriately labelled primary and secondary containers, or be rendered non-viable using an appropriate method[5].

A.7.2. The Transport In-Charge should be notified of the release by telephone or email within 24 hours of the determination that a release has occurred.

A.7.3. The location of an accidental release must be marked and, if the release occurs outdoors, the location must be monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable using an appropriate method. The period of monitoring will be determined in consultation with RCGM/GEAC.

A.7.4. 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.7.5. Any other corrective actions will be determined in consultation with RCGM/GEAC.

5.2 Storage

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 locked 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. 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.2.7. Any sample of regulated plant material removed from storage for the purpose of disposal must be rendered non-viable using an appropriate method.

B.2.8. Areas or units designated for storage of regulated plant material must be cleaned immediately following the period of storage. If uncontained plant material is discovered during cleaning, it will be handled in accordance with the requirement of Section B.7 of this SOP.

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 locked door securing 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

[5] Appropriate methods include autoclaving, dry heat (170C for 60 minutes), incineration or other methods approved

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 CFT 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 either be retained, using appropriately labelled primary and secondary containers, or be rendered non-viable using an appropriate method.

B.7.2. The location of an accidental release must be marked and, if the release occurs outdoors, the location must be monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable using an appropriate method. The period of monitoring will be determined in consultation with RCGM/ GEAC.

B.7.3. The Transport In-Charge should be notified of the release by telephone or email within 24 hours of the determination that a release has occurred.

B.7.4. 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.7.5. Any other corrective actions will be determined in consultation with RCGM/GEAC.

B.8. Sample Storage Label

THIS STORAGE AREA CONTAINS REGULATED 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 number _____

Telephone number _____

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

6

Planting and Maintaining the CFT

The Standard Operating Procedure for the Management of CFTs describe how the field trial is to be planted and how conditions of reproductive isolation for the plants are to be established and monitored throughout the growing season. These procedures also describe how the field is to be marked and what information must appear in the site map. Corrective actions, in the event of an accidental release, are also described.

6.1 Planting the CFT

C. Standard Operating Procedure (SOP) for the Management of CFTs of Genetically Engineered Plants

C.1. Scope

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

C.2. Requirements for Planting CFTs (All Crops)

C.2.1. All equipment and tools used to seed or plant CFTs 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 using an appropriate method.

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 the guideline.

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 CFTs conducted at the trial site and the authorization under which the CFTs were approved.

Monitoring Best Practice

The notice board should also include a copy of the trial map or a description of all the physical features of the trial site, as required in the permit approval letter.

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 CFTs (All Crops)

C.3.1. All corners of each trial site will be clearly marked with easily visible physical markers to permit identification of the trial site during the period of the trial and the post-harvest period. The markers should be made of materials that

will last for the entire duration of the CFT and post-termination monitoring 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 either be removed, using appropriately labelled primary and secondary containers or be rendered non-viable using an appropriate method.

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. When imposed, isolation distances are crop specific and prescribed by RCGM/GEAC in the letter of approval or permit for the CFT.

6.2 Minimum Isolation Distances of Crops Prescribed in India under CFTs

Isolation distances prescribed by the regulatory authorities are based on accepted distance for pure seed production, which have been prescribed under the Indian Minimal Seed Certification Standards by Department of Agriculture and Cooperation, Ministry of Agriculture. Some of the distances prescribed for some of the crops are as under:

Crop	Minimum isolation distance
Cotton	50 m
Maize	200 m
Rice	10 m
Okra	250 m

C.3.4. The reproductive isolation methods used must be continuous and completely surround the confined trial site.

C.3.5. The Trial In-Charge must ensure that the trial site and any surrounding spatial 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).

Monitoring Best Practice

The monitoring team should obtain and review records of periodic trial site monitoring by the Trial In-Charge. These records demonstrate that the Trial In-Charge is actively managing the confinement conditions of the trial.

C.3.6. Any prohibited plants within the isolation area must be destroyed 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 area must be rendered non-viable at the trial site using an appropriate method.

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 Reproductive 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.

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 using an appropriate method at 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. be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and 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 Reproductive Isolation for each trial site will be retained by the Trial In-Charge.

C.7.3. All records associated with the management of CFTs 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 CFT 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

Monitoring Best Practice

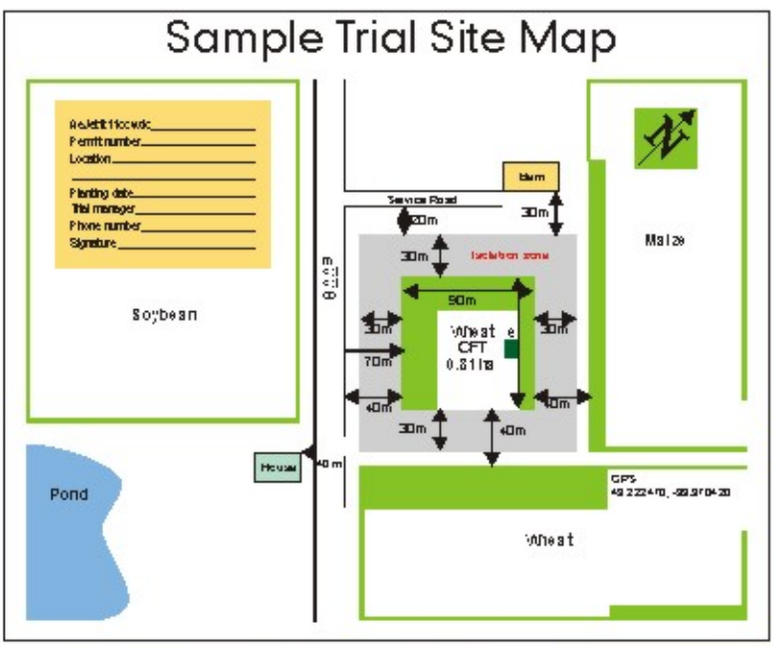
The monitoring team should review all records and reports required under the terms of the permit approval letter.
In addition, the team should review any supplementary records that have been maintained by the Trial In-Charge. Although certain records are required by the regulations, other records may be kept by the Trial In-charge as part of the data collection process associated with the CFT to record information such as phenotypic observations and efficacy of the GE trait. The Trial In-charge may also maintain records to assist with CFT management decisions.

the regulated material is authorized for commercial release: Record of Planting, Record of Reproductive Isolation, Record of Corrective Action (when applicable).

6.3 | Trial Site Map

A comprehensive, accurate map of the CFT site, including the surrounding area, is one of the most important risk management tools that a Permitted Party can produce. Maps are also extremely useful in monitoring trial sites during the trial period and post-harvest periods, because maps provide a concise overview of the site, and they can also communicate to the monitor how the Permitted Party intends to use the site in the course of the field trial. In India, the applicant is required to prepare a map as a part of the Record of Planting; however, the applicant may prepare additional maps for specific purposes, such as documenting pesticide applications or to record how the trial was harvested. These additional maps can also assist the monitor in understanding how the field trial was managed, so whenever possible, the monitor should ask to see all the maps that have been produced by the applicant. In India, maps of CFT sites must be prepared according to the following instructions:

1. Maps of CFTs 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 and 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.
   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. Labels on all fields within the isolation area by the common name of the crop.
   g. Indication of any fields of same/related crops that fall within, or border on, the isolation area.
   h. Identification of 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.



7

Reproductive Isolation Methods

7.1 Introduction to Reproduction Isolation

Reproductive isolation is the use of barriers of various types to prevent hybridization between two plants that would otherwise be sexually compatible. In the case of a CFT, the goal is to prevent pollen from the regulated GE plants in the trial from reaching sexually compatible plants outside the borders of the trial (Table 1). Effective methods of reproductive isolation are determined by the reproductive biology of the plant species, and their application is generally crop-specific.

In monitoring the Permitted Party's use of reproductive isolation methods, the monitor must verify that any isolation methods prescribed by the regulators are being used effectively and consistently by the Permitted Party throughout the period of time when the regulated plants are producing flowers and pollen. Monitors should verify that the Trial In-charge fully understands the reproductive isolation methods that have been chosen for the CFT, how those method work, what circumstances could cause a failure of isolation, and how to respond to an identified failure of isolation. If there are any failures of reproductive isolation during the course of the field trial, the Trial In-charge must review all of the CFT management practices to determine how the failure occurred and determine whether effective mitigation is available.

Each confined trial site should employ at least one continuous method of reproductive isolation. For example, the use of spatial isolation along three borders of a trial site and pollen trap rows along the fourth side would not be acceptable. However, additional or backup methods of reproductive isolation are acceptable (e.g., pollen trap rows along all four borders plus a surrounding spatial isolation distance). Some of the more commonly used reproductive isolation methods are described below.

7.2 Spatial Isolation

Field trials of regulated GE plants may be reproductively isolated from other plants of the same species or from sexually compatible relatives by establishing and maintaining a minimum isolation distance specified by the regulatory authority. The isolation distance must be kept free from any other plants of the same or related species (i.e., prohibited species). The regulatory authority may stipulate the prohibited species or it may be up to the Permitted Party to be aware of what, if any, sexually compatible relatives are known to be present in the area surrounding the field trial. Any prohibited plants found in the isolation distance must be removed before flowering or seed set (depending on the requirements of the regulatory authority) and rendered non-viable using an appropriate method at the trial site. For example, in Figure 5, reproductive isolation for a 400 square meter

Crop	Examples of Sexually Compatible Relatives
Mustard (*Brassica juncea*)	*B. rapa, B. napus, B. carinata*
Cotton (*Gossypium hirsutum*)	*G. barbadense*
Rice (*Oryza sativa*)	*O. rufipogon, O. nivara*
Sorghum (*Sorghum bicolor*)	*S. halapense*
Sugarcane (*Saccharum officinarum*)	*S.* spp.
Wheat (*Triticum aestivum*)	*T. turgidum* ssp., *Aegilops* spp.

CFT of GE cotton is provided by a 50 meter spatial isolation zone. The Trial In-charge will have to ensure that no cotton plants of any kind grow in the space between the border of the CFT field in the center and the edge of the larger square.

Spatial isolation is the default method of reproductive isolation, and it can be used with any crop. It will be the method used to re-establish reproductive isolation should there be a failure of any alternative method used.

If any prohibited plants are allowed to set seed in the isolation distance, then a breach of reproductive isolation will have occurred. To ensure that prohibited plants do not become established in the isola-tion zone, the area within the isolation distance will typically be included in the area subject to postharvest restrictions (which normally would only include the trial site proper). In Figure 6, flowering cotton plants have been found growing in the spatial isolation zone. This is a breach of reproductive isolation, and now the Trial In-charge must treat the entire 14,400 square meters as if it were part of the confined field trial during the post-harvest restriction period. This is 36 times as much land as was in the original CFT. For this reason it is advisable that Trial In-charges ensure that they will be able to maintain control over the spatial isolation zone during both the trial period (current season) and the post-harvest period, and that there are sufficient personnel and resources to monitor the isolation zone.

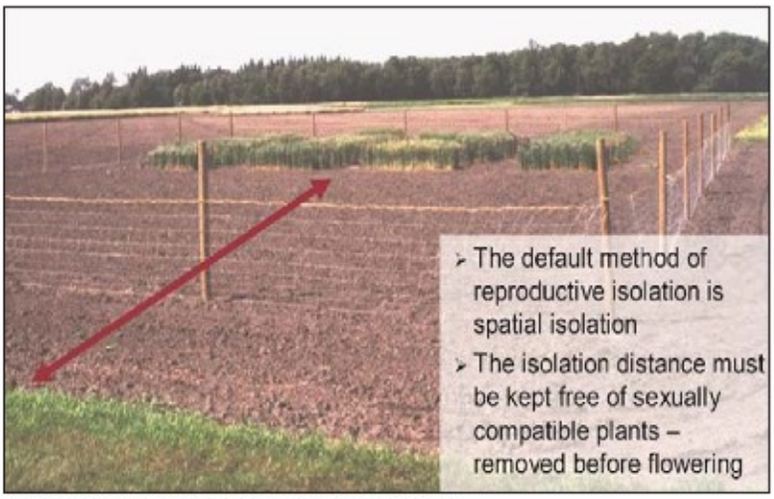


Figure 4 : Photo showing spatial isolation in use

7.3 | Temporal Isolation

With some crops, such as sugar beet, reproductive isolation of trial sites may be achieved by

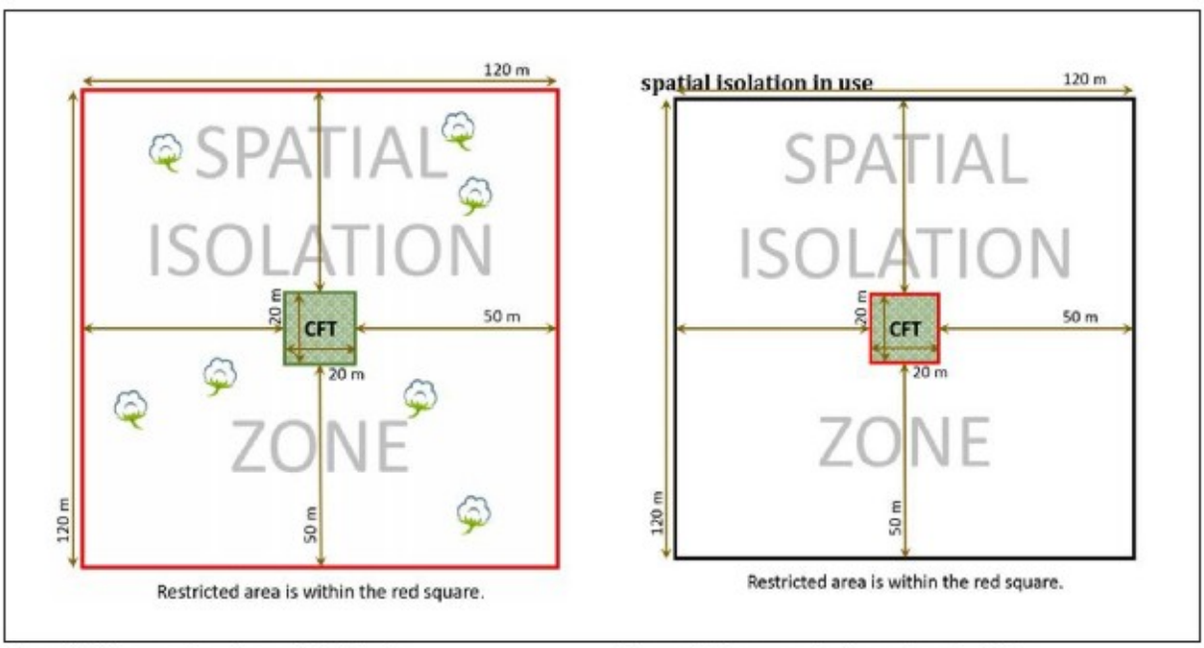


Figure 5: Diagram showing spatial isolation used in a cotton CFT.

Figure 6: Diagram showing a breach of the spatial isolation zone.

temporal isolation. This requires staggering the planting of the field trial so that anthesis by the GE plants is completed in its entirety either before or after anthesis of any sexually compatible plants that may be within the spatial isolation distance. Temporal isolation must be used cautiously, and in many environments it is not recommended because of the inherent variability in growing conditions that makes accurate prediction of the time to anthesis impossible. In order for temporal isolation to be effective, a regular system of monitoring must be undertaken to ensure that anthesis of regulated plants is not concurrent with anthesis of adjacent non-trial plants of the same species. If anthesis of the trial and non-trial plants is concurrent, a breach of reproductive isolation will have occurred.

If a breach of temporal isolation has occurred, the Permitted Party should inform the regulatory authorities immediately to determine if reproductive isolation can be established by spatial isolation.

7.4 | Removal of Floral Structures

Field trials may be reproductively isolated from plants of the same or sexually compatible species growing within the isolation distance by removing the flowers, or only the male flowers (e.g., maize tassels) from the regulated GE plants prior to pollen shed. As with temporal isolation, timely removal of flowers requires a rigorous monitoring program to be in place to ensure that all inflorescences are removed before anthesis. Unless the Regulatory Authority has given express authority to retain the removed flowers, they must be rendered non-viable using an appropriate method at the trial site, just like any other regulated plant material.

If the flowers of the regulated plants are allowed to shed pollen before they are removed, a breach of reproductive isolation will have occurred.

Figure 7: Photo of temporal isolation in use. The two corn fields were planted at different times.

In such situations, the Permitted Party should inform the regulatory authorities immediately to determine if reproductive isolation can be established by spatial isolation.

7.5 | Bagging

Field trials of GE plant species such as rice may be reproductively isolated from related species growing within the isolation distance by placing bags over the inflorescences of all the trial plants prior to anthesis, in order to prevent pollen shed and dispersal. The inflorescences must remain bagged until anther desiccation is complete. If the inflorescences of the trial plants are allowed to shed pollen before they are bagged, a breach of reproductive isolation will have occurred.

Where the inflorescences of regulated plants are not bagged prior to anthesis or if the bags are removed prior to anthesis, the Permitted Party should inform the regulatory authorities immediately to determine if reproductive isolation can be established by spatial isolation.

7.6 | Pollen Trap Rows

Field trials of some insect-pollinated GE plant species (e.g., cotton or oilseed rape) may be reproductively isolated from the same or related

species growing within the isolation distance by planting an uninterrupted, perimeter border of the conventional plant species. The width of the border row (alternatively called "guard rows" or "pollen trap rows") is species-specific, and the Permitted Party and Trial In-charge should consult with regulatory authorities to determine if border rows are effective and appropriate for a specific species and, if so, how wide they should be planted.

Typically the variety used to plant the border row should be a conventional variety that will flower concurrently with the GE plants in the field trial and be planted at a density comparable to the trial plants. The Trial In-charge should monitor emergence of border rows closely and replant promptly if the stand is inadequate. In order for border rows to be effective, regular and frequent monitoring must be undertaken to confirm that anthesis of both the experimental and border row plants is concurrent.

Border rows raise specific management challenges such as the movement of field equipment through the rows, and remediation if flowering of the border variety is asynchronous with the trial plants. Additionally, if the experimental plant is expressing a herbicide tolerance trait that is not shared by the border row variety, great care must be taken to ensure that the herbicide-susceptible border row is not affected if the herbicide is applied to the trial plants.

If the border rows are not maintained as above, and reproductive isolation is breached, the Permitted Party should inform the regulatory authorities immediately to determine if reproductive isolation can be established by spatial isolation.

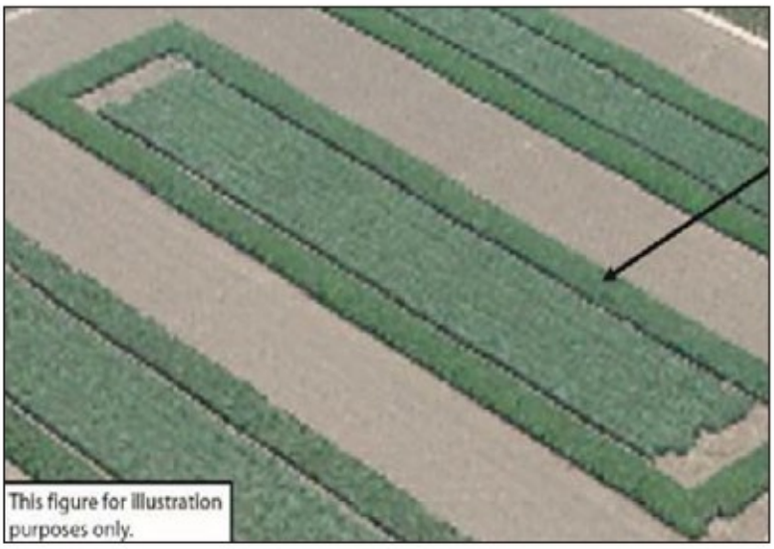


Figure 8: An example of pollen trap rows in use.

7.7 Early Termination

If it is compatible with the experimental objectives, early termination, including destruction of the trial plants prior to anthesis and pollen shed is a method of reproductive isolation that can generally be applied for all plant species. The Trial In-charge must carefully monitor the growth of the GM plants to determine when to terminate the trial. Unexpected environmental conditions may accelerate the growth of the plants, creating a risk that the plants may flower and shed pollen before they can be destroyed. If the inflorescences of the trial plants are allowed to shed pollen before the trial is terminated, a breach of reproductive isolation will have occurred, and the Permitted Party should inform the regulatory authorities immediately to determine if reproductive isolation can be established by spatial isolation.

8

Harvest and Disposition of Regulated GE Plant Material

The harvest of CFTs of regulated GE plants needs to be carefully managed. Trials should be harvested in such a way as to prevent the accidental release of the regulated GE plant material and their persistence at the trial site. It is advisable for everyone involved in the harvest of CFTs to review the letter of authorization and permit conditions to ensure that all regulatory requirements can be met. As with the trial itself, no plant material from the trial can be allowed to enter the human food or animal feed chains without prior consultation and approval by the appropriate regulatory authorities.

8.1 Harvest of GE Plant Material

D. Standard Operating Procedure (SOP) for the Harvest or Termination of CFTs of Genetically Engineered Plants

D.1. Scope

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

D.2. Requirements for Harvest of CFTs

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

D.2.2. All equipment and tools used during harvest or termination of CFTs 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 using an appropriate method at 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 GE Plant Material

D.3.1. Plant material from a CFT site, including border rows, if planted, that is not retained for research purposes will be rendered non-viable using an appropriate method at 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 using an appropriate method at 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 CFTs 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 CFTs 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 CFTs 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).

8.2 Post-Harvest Management

Regulatory authorities generally place restrictions on how land planted with CFTs can be used following trial harvest. These restrictive post-harvest measures are designed to ensure that any volunteers emerging after trial harvest are eliminated from the trial site to prevent the establishment of the regulated GE event in the environment and to ensure that no regulated plant material is allowed to enter the human food or animal feed chains. This section provides information about practices that can be undertaken to contribute to the safe management of confined field trial sites after harvest.

8.3 Disposition of GE Plant Material

E. Standard Operating Procedure (SOP) for the Post-Harvest Management of CFTs of Genetically Engineered Plants

E.1. Scope

E.1.1. This SOP applies to all CFTs 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 because regulated plants may be present as volunteers.

E.3. Requirements for Post-Harvest Management of Trial Sites, Case by Case, as Specified by Regu-latory 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 CFTs 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 or similar looking species as was planted during the CFT.

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-viableusing an appropriate method at 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.

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 using an appropriate method at 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 fax 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 CFTs 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).

9

Introduction to the Monitoring CFTs

9.1 Role of Monitoring in the Management of CFTs

As detailed in Chapter 4, risk management, when properly done, ensures that the GE plant will not escape from the field trial site and become established in the environment or co-mingle in the food/feed supply. This reduces the exposure factor to an insignificant level, and thereby reduces risk to an insignificant level. These risk management provisions create a system of controls that allow regulated plants to be safely tested and evaluated on a small scale. Therefore, one of the most important considerations in the evaluation of an application for a confined field trial is the Permitted Party's ability to satisfactorily implement an appropriate risk management program throughout the course of the CFT.

This is also the driving force behind the monitoring of CFTs—trained monitors are needed to verify that the Permitted Party is correctly carrying out all the required risk management practices to ensure that the field trial will not result in adverse environmental or food safety impacts. As explained, risk management is a comprehensive process, with steps that are implemented before the field trial is planted, steps implemented during the course of the field trial, and steps that are implemented after the field trial has been harvested. The proper monitoring of CFTs ensures that all these steps are performed correctly and in a timely way.

9.2 Terms of Reference for Monitors

The Central Compliance Committees (CCCs) constituted by RCGM/GEAC are authorized to monitor confined field trial sites for the purpose of ascertaining compliance with the terms and conditions of authorization. These committees also have the authority to inspect contained facilities that may be used for the storage of regulated genetically engineered plant material. An Office Memorandum is issued indicating the names and terms of reference of the monitoring team. Copy of this communication is also sent to the Permitted Party and must be available for presentation to the Trial In-charge, or Facility In-Charge, during the site visit. The Trial In-Charge or Facility-In-Charge (for storage facilities) may accompany the monitoring teams on inspections; however, the coordination of such activities is the responsibility of the Permitted Party.

The following terms of reference shall apply to all monitors.

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.

Fair Presentation

The findings, conclusions, and reports of monitoring teams shall 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 shall be recorded in the final report.

Due Professional Care

Monitoring teams shall 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.

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 are to be based only on the observations during their visit.

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.

9.3 Authorized Role of the Monitoring Team

Remember that the monitoring team is acting under the authority of the RCGM/GEAC, and its responsibilities under that authority are limited to

- determining whether prescribed risk management measures are being implemented correctly, consistently, and effectively
- accurately recording the documentary evidence regarding potential lapses in risk management to provide regulators with sufficient information to determine if regulations have been violated
- recommending appropriate remedial measures to the Trial In-Charge to restore effective risk management of the trial, in accordance with the regulations and the permit conditions
- reporting findings and recommendations to the RCGM/GEAC

Monitoring Best Practice

The team may, and should, advise the Trial In-Charge as to the severity of a particular lapse in risk management, and should impress upon the Trial In-Charge the urgency with which particular remedial measures be completed.

At the same time, there are certain activities that are outside the responsibility of the team and should not occur during the course of an inspection.

- Unless the monitoring team contains regulatory personnel, the focus of the team should not be to determine whether or not a particular activity is in fact an actual violation of the regulations.
- The team should not give legal advice to the Trial In-Charge.
- The overall experimental design and specific experimental protocols used to collect data have already been reviewed by RCGM/GEAC, so the team should not critique the experimental design, unless the criticism is directly related to risk management.
- The team should not question the use of particular DNA sequences, traits, or crop varieties.

10

Monitoring Process

Effective monitoring is tailored to the specific circumstances of the field trial. Factors such as the size and location of the trial, the crop species, and the genetically engineered trait or traits being tested will help determine timing and frequency of the monitoring as well as how the monitoring is conducted. Typically, monitoring occurs at critical stages of the trial—pre-planting, planting, pollination, harvest, post-harvest, termination, and post-termination—in order to observe how the terms of compliance are being observed at each stage.

Once a delegated agency has made the decision to monitor a confined field trial or storage facility to ascertain compliance with the terms and conditions of authorization, a series of steps must be taken in sequence to ensure that monitoring is conducted thoroughly, consistently, and in accordance with all applicable regulations and guidelines. The process begins with the constitution of Central Compliance Committees by RCGM/GEAC and an Office Memorandum is issued indicating the names and terms of reference of the monitoring team. Copy of this communication is also sent to the Permitted Party.

Monitoring should go beyond a simple "snapshot" of the trial at the time of the monitor's visit. The monitors should first review the evidence that prescribed risk management measures are being practiced effectively. At the same time, monitors should attempt to determine whether the present state of the trial indicates that risk management measures were not effectively used in the past.
Lastly, and perhaps most importantly, the monitoring process should identify current practices or circumstances that, if any, could lead to a failure of effective risk management in the future.

Monitoring Best Practice

Each field trial should be inspected at least twice over the course of the trial, but more frequent inspections are always preferable, especially when the Permitted Party does not have extensive experience conducting trials or when the GE plant in question raises novel challenges regarding confinement.

10.1 Preparation for the Site Visit

Prior to conducting any assessment, the members of the monitoring team should review and understand the following documents:

- Guidelines for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India
- Standard Operating Procedures or performance standards implemented during conduct of the field trial
- Terms and conditions of authorization attached to the letter of permit
- Any applicable prior monitoring reports
- In the case of monitoring of confined field trial sites, monitoring teams should familiarize themselves with the confined field trial maps.

Monitoring Best Practice

The trial site map is one of the most important documents that the monitoring team should have during their inspection of a CFT. The team should ensure that the map contains all the details required in the permit approval letter.

In addition to material for recording observations (i.e. checklists and/or monitoring forms), accessories such as a measuring tape, digital camera, sampling containers, etc. may be required, depending on the audit activity.

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. 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.

Depending on the nature of the field trial, various pieces of evidence can help the monitor verify that the Permitted Party is effectively managing risks associated with the field trial:

- Direct observation of the field trial site
- Direct observation of the personnel as they carry out various activities
- Official records maintained by the Permitted Party pursuant to government-issued Standard Operating Procedures
- Unofficial crop management records maintained during the trial
- Any other operating procedures followed by the Permitted Party
- Personnel training materials and training records
- Interviews with personnel

10.2 Document 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 work with the Facility In-Charge or Trial In-Charge to identify and review appropriate 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)
7. Any records related to compliance or corrective actions (Record of Corrective Action)

10.3 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. These inspections may be performed either prior to or after regulated plant material has been shipped or moved to the storage facility.

To prepare for a facility inspection, the Standard Operating Procedures (Chapter 5, Sections A and B) should be reviewed. Any documents

associated with the authorized activity including the following may also be reviewed:

- Records of Transport
- Records of Storage Inspection and Inventory
- Containment requirements specific to the facility, building, or location to be inspected

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. Regulated plant material is stored in appropriately labeled containers that will prevent the inadvertent release or loss of the material
3. Access to storage areas is limited to authorized personnel and there must be evidence of some active access control system
4. 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
5. The storage area is clearly marked as containing regulated plant material, and used exclusively for that purpose
6. All regulated plant material in storage is recorded on an inventory record, which also records all additions to, or removals from storage
7. Storage facilities are checked regularly to ensure they are secure, free of any waste, animal pests, 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.

Any failure to follow the above requirements should be noted in the inspection report. Such failures may indicate existing compliance issues or potential future compliance issues.

10.4 CFT Site Inspections

Risk assessors evaluate confined field trial applications and determine permit conditions that the Permitted Party must follow in order to be granted approval for the trial. CFT permits include detailed information regarding procedures to ensure that the regulated plant material is confined at the trial site, as well as prescribed methods for final disposition of the regulated plant material. The goal of permit conditions is to provide for the management of the trial so that regulated plant material will not persist in the environment or co-mingle with food or feed. To prepare for a facility inspection, the monitoring team should review the Standard Operating Procedures (Chapter 6). Before conducting the inspection, the team must review any documents associated with the authorized activity, including

- The official copy of the authorized permit
  - Monitors should be familiar with the identity of the regulated plant material described in the permit. Only plant material described in the permit may be planted at the field trial site.
  - Check the release or planting date specified in the permit to confirm that the inspection is occurring within the period described for the field trial.
- Any permit conditions that have been approved by the risk assessors.

- Any standard operating procedures and other protocols that have been proposed by the Permitted Party and approved by the risk assessors.
  - ☐ Familiarize yourself with the experimental design.
  - ☐ Identify all of the confinement measures that will be used in the course of the field trial and how they will be maintained.
  - ☐ Understand how any regulated plant material will be disposed at the end of the trial.

During the inspection, the monitoring team should review any field manuals or notebooks that have been prepared by the Permitted Party to guide or record day-to-day activities at the trial site and ensure that all activities comply with the permit requirements. The team should verify that the activities recorded in the notebooks have actually taken place.

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

- **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 are in accordance with the prescribed procedures.
- **During the period of crop flowering and prior to seed set** – this is the most critical stage 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)
- **During the post-harvest period** – to verify if the area under post-harvest restrictions is free of prohibited plants and if appropriate monitoring activities are being performed and documented

10.5 Specific Considerations in Different Phases

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

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 and that the size of the trial is no larger than the size specified in the permit approval letter.

Reproductive Isolation

Regulated GE plants in the CFT must be reproductively isolated from any neighboring 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 at least one continuous method of reproductive isolation.

Spatial Isolation

Spatial isolation is the standard method used for ensuring reproductive isolation of plants in the

Monitoring Best Practice

The monitoring team should use photographs in the course of the inspection to record management practices used at the site, to verify the layout of the site, and to docu-ment possible compliance problems, especially when a verbal account would be inadequate.

CFT. All plants in the trial (e.g., regulated GE 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 regu-latory authorities 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 the trial, and it must be continu-ous 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
- 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 (destru-ction by approved methods) of any prohibi-ted plants found during routine monitoring

Temporal Isolation

With this method of reproductive isolation, the GE plants in the trial and any sexually compatible plants in the vicinity cannot be in flower at the same time. The monitoring team must therefore verify the following:

- The locations of any neighboring fields conta-ining the same or a sexually compatible crop must match what is shown on the trial map.
- The flowering status of the GE plants and sexually compatible plants in neighboring fields is being monitored by the Trial In-charge as required by the permit conditions and recorded in the Record of Reproductive Isolation.
- The GE plants and sexually compatible plants in neighboring fields are not flowering concurrently.

Bagging or Removal of Floral Structures

It is essential that these methods of reproductive isolation be performed completely, prior to pollen shedding by the GE plants. The monitor-ing team must verify the following:

- Field workers have been properly trained in either flower bagging or rem oval.
- Flower bagging or removal has been accomplished completely, with no overlooked plants or flowers.
- The Trial In-charge has recorded in the Record of Reproductive Isolation the dates when bagging or flower removal activity occurred and dates when the trial was moni-tored for flower emergence.

Pollen Trap Rows

For pollen trap rows to be an effective means of reproductive isolation, the plants in the trap rows must be carefully maintained throughout the growing season. The monitoring team must verify the following:

- The plants in trap rows must be planted at an appropriate distance from the GE plants and at t100 same density as the GE plants, as required by the permit conditions.
- The plants in trap rows must be maintained in a healthy condition, so that flower produc-tion will be adequate to attract pollinators.
- The pollen trap plants must be flowering at the same time as the GE plants.
- The Trial In-charge is recording all monitoring activity performed on the pollen trap plants in the Record of Reproductive Isolation.

Early Termination

Although early termination is a relatively simple process, proper timing is of the essence when

early termination is used for reproductive isolation. The monitoring team must verify the following:

- The Trial In-charge is regularly monitoring the growth of the plants in the trial to ensure that the plants will not flower prematurely.
- All GE plants are destroyed in the termination process
- The Trial In-charge is recording all monitoring activity performed on the CFT to prepare for early termination in the Record of Reproductive Isolation.

Termination, Harvest and Disposition

At the termination of the CFT, 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 GE 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, and high-pressure water. Any plant material recovered must be rendered non-viable by burning or burial on the trial site
- All GE 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
- 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

Monitoring Best Practice

It is crucial that trial termination and harvest processes are monitored. It is during these periods when there is the greatest risk that GE plant material could be mishandled and either escape from the trial site or enter the food/feed supply.

Post-Harvest Period

All confined field trial sites are subject to a mandatory period of post-harvest land use restriction. The duration of this period is crop-specific and determined by the RCGM/GEAC, and stipulated in the terms and conditions of authorization. The post-harvest inspection primarily addresses control of regulated GE plant material following harvest, the condition of the field site after harvest, and monitoring for the presence of volunteer plants in the trial site, and control for standard release permits and notifications. To prepare for a facility inspection, the monitoring team should review the Standard Operating Procedures (Chapter 8).

Monitoring during the post-harvest period should include

- Processing, storage, and transport/shipping of harvested material
- Devitalization and disposition of regulated plant material
- Site condition following harvest
- Site markers
- Volunteer monitoring and control
- Harvest and processing equipment cleaning

During post-harvest monitoring the monitoring team should ask questions based on the permit conditions and any authorized standard operating procedures or protocols. As always, the goal of the permit conditions and any additional SOPs are to create a risk management system which ensures that the regulated plant material will not persist in the environment or co-mingle in food and feed. 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.

10.6 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.

To ensure that the report is complete and accurate, the monitor may include a variety of information:

- Documents maintained by the Permitted Party and Trial In-Charge
- Photographs of plants, labels, buffer zones, storage facilities, and equipment
- Annotated sketches, when photographs are not available
- References to the trial site map or GPS coordinates, as appropriate

10.7 Documenting and Reporting Risk Management Failure

The monitoring report should fully and accurately describe any instances of risk management failure. The following pieces of information should be included in the report:

- A description of management failure, including an explanation of how the failure occurred
- The location, date, and time of the failure
- The names and roles of any persons involved in the failure
- A description of any corrective actions taken or preventative measures suggested by the Permitted Party
- Other observations, as appropriate

Not all risk management failures are of equal significance, and certain failures may have more serious consequences than others. Monitors should take specific note of any circumstances indicating that any of the following failures have occurred or are likely to occur:

- Volunteers of the regulated plant in a field of non-regulated plants of the same species
- Regulated plants found persisting outside the trial site
- Regulated plants being used as food or feed

- Regulated plants being handled in a way that could enable the commingling of the plants with food or feed
- Large spills or unintended releases of regulated plant material
- Regulated plant material being stored under circumstances where loss of the material or commingling with non-regulated material is likely

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. 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 the instructions from Regulatory Authorities, the monitoring team will communicate both verbally and in writing within 24 hours to the Trial In-Charge (or Facility In-Charge) and the Permitted Party.

A Record of Corrective Action, detailing the inci-dent 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 noncon-formities 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.

11

Non-compliance and Corrective Action

11.1 Failure to Implement Prescribed Risk Management Measures

The complexity of planning, establishing, managing, and terminating a confined field trial is compounded by the fact that a CFT is both a scientific experiment and a series of rigorously regulated activities. As an experiment, the trial must meet the standards of any piece of research: scientifically meaningful hypothesis, treatments and experimental conditions designed to test the hypothesis, and valid controls.

Some of the regulatory lapses discovered during the monitoring process will be minor and easily corrected, such as a missing piece of information on a signpost, or they may indicate a fundamental failure of confinement of the trial, such as allowing the regulated GE plant to escape into the environment or food supply.

The job of the monitoring team is twofold: (1) the identification of possible failures of regulatory compliance and (2) the detection of lesser problems in the execution of the trial that may, if left uncorrected, lead to more significant problems, including regulatory infractions or even a breach of trial confinement. With each visit to a confined field trial, the monitoring team must be prepared to exercise this dual role.

11.2 Recommending Appropriate Corrective Measures

During the course of a site inspection, the monitoring team may identify a risk management lapse. When this happens, the team must be ready to advise the Trial In-Charge as to how to remediate the problem. The goal of remediation is to restore confinement of the field trial, but each CFT is unique, and it is impossible for the monitoring team to anticipate every possible risk management failure and how to remediate it. Instead monitors must be well-versed in the full range of appropriate and effective risk management measures for CFTs, so when faced with a lapse, the team will be able to identify remedial actions that have a reasonable likelihood of quickly and effectively correcting the lapse. The ability of the monitoring team to respond to instances of non-compliance appropriately, given the unique circumstances of a particular CFT, will develop over time. Table 2 provides examples of appropriate remediation for specific risk management lapses. Monitoring teams should use these examples as guidance and not as a list of the only or the best corrective actions to recommend.

Monitoring Best Practice

Before recommending a corrective action, team members should discuss the matter among themselves and with the Trial In-Charge to determine which action has the greatest likelihood of success.

One of most important goals for CFT monitoring is to detect minor lapses in risk management and correct them before they impact the confinement of the trial. The corrective actions listed in the table above should serve as a reminder to the monitoring team that when risk management systems fail to the extent that

Monitoring Best Practice

Identifying and remediating small problems before they become big ones is the best way to help avoid these costly outcomes and to maintain the public's trust in the regulatory system.

Table 2:
Examples of Risk Management Lapses and Appropriate Remedial Actions

Lapse in Risk Management	Appropriate Correction or Remediation	Comments
Storage of GE Plant Material		
Storage area is not secure	Lock the storage area.	
Storage containers are not labelled or are improperly labelled.	Verify the identity of the material in the container and place proper labels on the container.	If the identity of the material can not be determined, it may need to be destroyed.
GE plant material has spilled from storage containers or containers are leaking.	Recover spilled material; destroy or return material to container, as appropriate.	
	If the spill occurs outdoors, the spill site must be monitored for volunteers.	
Trial Site Confinement and Reproductive Isolation		
CFT has not been authorized by the RCGM/GEAC	Destroy the GE plants immediately	Inform the RCGM/GEAC so that a post- destruction monitoring plan can be created.
Insufficient isolation distance; GE crop has not yet flowered	Move site markers to include a greater isolation distance appropriate for the crop.	If a larger isolation distance cannot be established and if other isolation measures cannot
	Implement other isolation methods such a flower bagging or detasseling.	be used effectively, the trial may need to be terminated.
Prohibited plants have been found within the trial site; plants have not yet flowered	Destroy plants immediately	Use disposition methods prescribed by permit approval letter
Prohibited plants have been found within the isolation distance; plants have not yet flowered	Destroy plants immediately	Use disposition methods prescribed by permit approval letter
Guard/Border rows are not fully filled with plants measures	Establish an isolation distance appropriate for the crop species	If an isolation distance cannot be established and if other isolation can not be used effectively, the trial may need to be terminated.
Guard/Border rows are not flowering co-synchronously with the GE plants	Establish an isolation distance appropriate for the crop species	If an isolation distance cannot be established and if other isolation measures cannot be used effectively, the trial may need to be terminated.
Bags covering male flowers or male flower parts are torn or missing trial may need to	Replace bags. Establish an isolation distance appropriate for the crop species	If an isolation distance cannot be established and if other isolation measures cannot be used effectively, the be terminated.
Early crop destruction is the method of reproductive isolation, but there are flowers on the GE plants	Establish an isolation distance appropriate for the crop species	If an isolation distance cannot be established and if other isolation measures cannot be used effectively, the trial may need to be terminated.
Temporal isolation has failed—GE plants are flowering at the same time as crops of the same species within the isolation distance	Establish an isolation distance appropriate for the crop species	If an isolation distance cannot be established and if other isolation measures cannot be used effectively, the trial may need to be terminated.
Detasseling/deflowering has failed—GE plants with flowers are found	Establish an isolation distance appropriate for the crop species	If an isolation distance cannot be established and if other isolation measures cannot be used effectively, the trial may need to be terminated.
Required security measures, such as fencing, are either missing, damaged, or improperly used	Security measures must be brought into compliance with the terms in the permit authorization letter	

Lapse in Risk Management	Appropriate Correction or Remediation	Comments
Disposal of GE Plant Material		
Disposal site does not meet requirements in permit approval letter Spills of GE plant material during disposal	Stop disposal activities. Modify site to meet requirements or create new site ▪ Recover and properly disposed of spilled material ▪ If the spill occurs outside, and the material cannot be recovered, the spill site must be monitored for volunteers.	
Post-Harvest Site Management		
Prohibited plants are found within the restricted area; plants have not flowered Prohibited plants are found within the restricted area; they have been allowed to set seed	▪ Destroy plants immediately and dispose of plant material according to the permit approval letter ▪ Destroy plants immediately and dispose of plant material according to the permit approval letter ▪ Extend post-harvest monitoring to monitor the site for volunteers and destroy them	
Record Keeping		
Required records are missing completely or crucial pieces of information are missing from existing records	properly incorporated in the required records	

reproductive isolation is compromised, the Permitted Party may not only incur significant financial costs to remediate the situation, but may also lose the opportunity to collect data from the CFT, should it be decided that the CFT must be prematurely terminated.

11.3 Post-Inspection Activities for the Monitoring Team

The monitoring team's report must include a list of all lapses in risk management systems that were noted during the inspection. Whenever the team recommends or requires remediation or corrective actions, they should provide a deadline by which time the actions are to be completed. Administrative matters should be corrected quickly, and may even be corrected during the course of the inspection, in which case the team should note the correction in the report. For lapses that may compromise effective confinement of the CFT, the team should recommend measures which, in the team's best judgment, will prevent escape of the GE plant into the environment or food supply. The team's report should, for each lapse of risk management, indicate which corrective measures were prescribed during the visit, whether it impacted confinement, and what deadlines were given to the Trial In-Charge to implement all the measures.

Monitoring Best Practice

The team should ask the RCGM/GEAC for guidance in dealing with specific types of lapses, for example, those with the potential to significantly undermine confinement or lapse for which there are a variety of possible corrective measures.

Before leaving the CFT site, the team should provide a copy of the report, when possible, but at a minimum, the Trial In-Charge should be presented with a list of the corrective measures recommended and the associated deadlines. The team should note on the list any corrective measures that were implemented during the site visit.

Monitoring Best Practice

Members of the team should decide upon a method to indicate their acknowledgement of a completed corrective action. For example, the team leader may sign or initial individual items, and also date each signature.

The Trial In-Charge should be encouraged to ask questions during the inspection and also during the review of corrective actions to be taken. The team should ensure that the Trial In-Charge knows exactly what actions need to be taken and why, so that the inspection becomes a learning process for the Trial In-Charge and a means to prevent similar lapse from occurring in the future.

11.4 Subsequent Visits to Ensure Corrective Measures Are Taken

After the inspection, the team should discuss the most effective times to return to the site to verify that all corrective measures have been implemented and that the CFT is fully in compliance with the terms of the permit approval letter.

Separator for Appendix

Appendix - I

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 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 att 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. _____ 3. _____

2. _____ 4. _____

Appendix - II

Glossary

Accidental Release

Any release of a regulated GE seed, whole plant, or plant part that is not in compliance with the terms and conditions of authorization. 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 flowering period of a plant, from the opening of the flower bud.

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.

Application

An application is the information/data package in prescribed format submitted for each regulated genetically engineered event intended for cultivation in a confined field trial. Multiple events of a single plant species may be included in a single application provided they have been transformed with the same construct. Applicants must use the “Application for Confined Field Trials” form to complete an application.

Authorization

A letter of intent or permit issued by the Regulatory Authority (RCGM or GEAC) to conduct any research experiment on GE plants under specified terms and conditions.

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.

Construct

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

Confined Field Trial

A CFT is a field experiment of growing a regulated, GE plant in the environment under specific 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 events 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. It is understood that the experimental plant/species/varieties/hybrids grown in confined trials are those that have yet to receive regulatory approval for environmental release from GEAC. This confinement is also to be understood in terms of confinement of a particular GE plant in a particular region, state, village or a research form of the Permitted Party and is not accessible by other parts of the country in environmental terms.

Embodied in this definition of confinement are three important considerations. Firstly, confined field trials are typically carried out on a small scale, usually to a maximum of one hectare (ha). There may be exceptions to this, e.g., the cultivation of larger areas so that sufficient plant material may be harvested for livestock feeding trials. Secondly, a confined trial is an experimental activity conducted to collect data on potential biosafety impacts. The collection of such field trial data is a prerequisite for safety assessment of the GE crop under evaluation. Additionally, field trials are carried out to produce sufficient plant material so that the developer can undertake research to address the information and data requirements for livestock feed and human food safety assessments.

Finally, the trial is conducted under conditions known to mitigate:

1. Pollen- or seed-mediated dissemination of the experimental plant.
2. Persistence of the GE plant or its progeny in the environment, and;
3. Introduction of the GE plant or plant products into the human food or livestock feed pathways.

As it is generally used within this document, “confinement” of a field trial refers to reproductive isolation, but depending on circumstances, may also include some degree of physical isolation. On a case-by-case basis, specific methods of physical confinement may also be advisable to prevent herbivory of the destruction of plant material by foraging animals, or the unauthorized harvest or removal of plant material by humans.

Contained Conditions

Contained conditions refer to work with GE organisms with contained facilities, such as a laboratory, a greenhouse, a nethouse, and areas used for the storage and handling of experimental GE organisms. Under contained conditions there is a physical barrier or barriers that contain material under research and development so there is virtually no direct contact of viable GE organisms with the environment. Activities carried out within such contained facilities are generally performed subject to specific biosafety guidelines and under specified levels of containment as detailed in Guidelines for Research in Transgenic Plants, 1998, wherein three different categories of containment levels have been defined for genetic engineering experiments on plants. These guidelines are primarily based on guidelines on containment issued by OECD.

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.

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.

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/GEAC.

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

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

Pollen Trap Rows (Guard Rows)

For insect-pollinated plants, a guard row is comprised of plants of the same species as the regulated GE plant grown around the perimeter of a confined trial as an alternative means of reproductive isolation. Guard rows serve to capture pollen from the confined trial and minimize the dissemination of pollen from GE plants to the same and/or related species. The width of the guard row is determined by the species of GE planted in the confined trial.

Primary Container

The container into which regulated plant material is placed.

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

Reproductive isolation refers to the means used to prevent movement of plant material, particularly pollen, from the confined trial. There are three principal methods used to achieve reproductive isolation: spatial separation, physical isolation, and temporal isolation.

Secondary Container

The container into which a primary container is placed.

Seed

Seed means any type of embryo or propagule capable of regeneration and giving rise to a plant of agriculture which is true to such type. The definition of the seed will be taken as per the rules applicable at that point of time.

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.

Site Map

Map of the trial site providing sufficient details on the dimensions, distances to physical landmarks, layout of the site etc. to allow regulatory officials/monitoring agencies to locate each field trial site during the planting season as well as during any required period of post-harvest land use restriction.

Transformation

The process of incorporating DNA into an organism's genome. There are several methods to do this in plants. The most commonly used methods for plant transformation are Agrobacterium-mediated transformation and biolistic transformation.

Transgenic

Relating to, or being an organism whose genome has been altered by the transfer of a gene or genes from another species or breed. In practical use, transgenic refers to any organism whose genome has been subject to artificial modification, such as through the use of recombinant DNA technology or genetic engineering. In this manual, the terms transgenic and genetically engineered are used interchangeably.

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 Protocol

The protocol for conducting a confined field trial approved by the Regulatory Authorities.

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.

Unconfined Environmental Release

As it is used in this document, unconfined release refers to the environmental introduction of a GE plant usually without the requirements for reproductive (or physical) isolation or post-harvest land use restrictions or monitoring for nearby related sexually compatible plant species. Generally, the authorization for unconfined release is a government regulatory decision that is based on the outcome of a comprehensive environmental risk assessment. Approvals for unconfined release may be indeterminate or they may be time- limited, with or without requirements for post-commercialization surveillance. Depending on the characteristics of the GE plant, there may also be requirements for insect resistance management plans or other specific post-approval risk management or stewardship measures.

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.

Important Contacts:

NATIONAL PROJECT DIRECTOR
Shri Hem Kumar Pande, Additional Secretary

NATIONAL PROJECT COORDINATOR
Dr. Ranjini Warrier, Adviser

Ministry of Environment, Forest and Climate Change, Govt. of India
Indira Paryavaran Bhawan, Ali Ganj, Jor Bagh Road, New Delhi - 110003

For further information, please contact at E-mail: biosafety-mef@nic.in