TOOLS FOR TRAINERS

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

सत्यमेव जयते

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Center for Environmental Risk Assessment

PHASE-II Capacity Building Project on Biosafety

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Nature Protects if She Is Protected

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE
Government of India

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

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Monitoring Confined Field Trials of Regulated, Genetically Engineered (GE) Plants: Tools for Trainers

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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सत्यमेव जयते

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MINISTER OF STATE (INDEPENDENT CHARGE)
पर्यावरण, वन एवं जलवायु परिवर्तन
ENVIRONMENT, FOREST & CLIMATE CHANGE
भारत सरकार / GOVERNMENT OF INDIA

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

Cont...

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 CERA ILSI 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

CONTENTS

1. PREPARING AND DELIVERING A TRAINING WORKSHOP

1.1 Introduction

Training of monitors (members of monitoring teams) is necessary for a robust system for monitoring of confined field trials (CFTs) of genetically engineered (GE) plants. This document provides tools for trainers for conducting training of monitors. The accompanying presentation slides and group exercises, were developed for 2-day intensive training workshops conducted as part of Phase II Capacity Building Project on Biosafety, based on the "Manual on Monitoring CFTs of Regulated, GE plants". The manual and the presentations cover three broad topics: (1) risk assessment and management of CFTs, (2) Indian guidelines for the management of CFTs, and (3) monitors role in the management of risks from CFTs.

1.2 Trainer's qualifications

Expected qualifications for the trainer include a Ph.D. degree in natural sciences or an equivalent combination of education and experience, experience as a regulator of GE plants, or as a senior scientist active in a scientific area relevant to the environmental risk assessment of GE plants. Examples of relevant areas include: molecular biology, plant breeding, and biochemistry.

The trainer is also expected to be familiar with both public and private sector research and development, and to have excellent language, communication and presentation skills, particularly to different audiences.

1.3 Target participants

The target audience includes regulators and scientists tasked with monitoring compliance of confinement and biosafety measures imposed on researchers conducting CFTs using GE plants.

Participant selection is key to the success of a CFT training workshop and therefore it is very important to identify carefully those **best to invite** with reference to the workshop objectives. Individual regulators/ scientists may be invited to the workshop directly or else the directors or senior administrators of specific institutions may be requested to nominate one or more participants. To help in selection of the appropriate participants, the suggested terms of reference for participants are as follows:

i. Participants should have previous field experience in agronomy, plant breeding, plant pathology; weed science, entomology or soil science.

ii. Members of institutional monitoring committees convened under the auspices of the Institutional Biosafety Committees (IBSC); Central Compliance Committees (CCC); State Biotechnology Coordination Committees (SBCC); District Level Committees (DLC); and monitoring teams from state agricultural universities should be specifically encouraged to participate in the training workshops for monitors.

iii. Participants should be familiar with the "Guidelines and SOPs for Conduct of Confined Field Trials of Regulated, GE plants, 2008" notified by the Ministry of Environment and Forests and the Department of Biotechnology. Participants may also be encouraged to complete the E-learning course "Compliance Management of Confined Field Trials" based on the above guidelines. The course is freely available online at http://cft.biotech.co.in/.

1.4 Sample agenda

An effective agenda is an important element of a productive workshop, as it communicates information regarding topics of discussion, presenters and time allocated for each topic and the focus of the meeting. Presentations and breakout sessions should be based on the requirements for monitors. A sample agenda is placed in the Box below:

Sample agenda for 2 day workshop

DAY 1		
Time	**Activity**	
09:00	09:30	Registration
09.30	10.30	Opening addresses • Participant introductions • Agenda overview
10:30	10:45	**Tea Break**
10:45	11:10	Regulation of Confined Field Trials of GE Plants under Rules, 1989
11:10	11:30	Assessment and Management of Risks Posed by Confined Field Trials
11:30	12:30	Group Exercise 1
12:30	12:50	Risk Management Methods for Confined Field Trials
12:50	13:45	Group Exercise 2
13:45	14:45	**Lunch**
14:45	15:05	Transportation and Storage of Regulated GE Plant Material
15:05	15:35	Group Exercise 3
15:35	15:50	**Tea Break**
15:50	16:20	Planting and Maintaining the Confined Field Trial
16:20	17:10	Group Exercise 4
17:10	18:00	Reproductive Isolation Methods
DAY 2		
09:00	09:15	Review
09:15	10:00	Group Exercise 5
10:00	10:30	Harvest and Disposition of Regulated GE Plant Material
10:30	11:00	**Tea Break**
11:00	11:30	Group Exercise 6
11:30	12:00	Introduction to Monitoring of Confined Field Trials
12:00	12:30	Group Exercise 7
12:30	13:30	Monitoring Process
13:30	14:15	**Lunch**
14:15	15:15	Group Exercise 8
15:15	15:35	Non-Compliance and Corrective Action
15:35	16:00	**Tea Break**
16:00	16:30	Group Exercise 9
16:30	17:30	Completing the Monitoring Report 17:30 17:45
17:30	17:45	Concluding remarks

1.5 Sample presentations and group exercises

The sample presentations are useful for organizers/ trainers when preparing for the workshop. Presentations corresponding to each chapter of the monitoring manual are provided in this document. At the bottom right of each slide, the section to which it corresponds has been mentioned. Sample group exercises have been included after each presentation in this document so that participants are given group activities or exercises to carry out, rather than being passive recipients of information through a more typical seminar or lecture format. The answer keys and the trainer's notes are also provided separately. Trainers may be encouraged to develop their own exercises based on sample exercises and trainer's notes.

To maximize the effectiveness of such training, it is suggested that the number of participants should be limited to approximately 20-25.

1.6 Evaluation

It is important to get feedback on the learnings from the workshop and the participant's experiences during the workshop and their plans for using the information. Accordingly, a sample quiz and sample workshop evaluation form are provided in the document. These can be used and adopted appropriately by the trainers.

1.7 Certificates

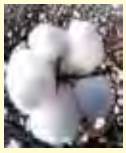
Certificates are used to certify the completion of the workshop by the trainees and to encourage their active participation in the workshop. As the trainee participants are expected to engage in the regulatory monitoring, the participants must attend the full two-day Workshop and certificates of completion should not be provided to participants who do not complete the entire course. Organizers may also consider awarding certification of completion, once they have completed the quiz and workshop evaluation forms.

1.8 Expected outcomes

Upon completion of training, using this document and the accompanying materials, the trained personnel should be able to participate as a member of a CFT monitoring team to assess the effective implementation of confinement measures for a CFT.

2. PRESENTATIONS AND GROUP EXERCISES

2.1 Regulation of Confined Field Trials of GE Plants under Rules, 1989



Dr. Ranjini Warrier
Director, MoEFCC & NPC Biosafety Project

Government Commitment

- Genetically modified organisms (GMOs) and products thereof are regulated in view of potential risks to human health and environment
- India has ratified the following International Environmental Agreements/Conventions/Protocols:
  - Convention on Biological Diversity (CBD), 1992.

  Cartagena Protocol on Biosafety (CPB) in January 2003.
  - Nagoya Protocol on Access and Benefit Sharing (ABS)
  - Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress in the context of CPB

Mandate of Ministries/Department

Ministry of Environment and Forests	• Primarily responsible for conservation and protection of environment, ensuring environmental and human health safety before release of LMOs.
Department of Biotechnology (Ministry of Science & Technology)	• Promotion of biotechnology. • Provide services in areas of research, infrastructure, generation of human resource
Ministry of Agriculture	• Policies aimed at agriculture growth. • ICAR responsible for monitoring agronomic benefits of GM technology. • Post release performance of GM crops.
Ministry of Health and Family Welfare	• Policies aimed at protecting and monitoring human health.
Ministry of Commerce and Industries Department of Customs	• Enhance trade with other countries through export/ import policies. • Enforcement at point of entry

Acts/Rules - Biosafety Regulation

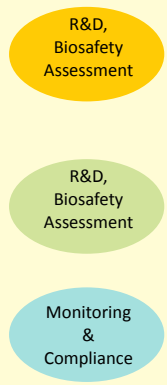
- Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms (HMO)/Genetically Engineered Organisms or Cells, 1989 under the EPA (1986) known as 'Rules 1989' by MoEF
- The Biological Diversity Act, 2002 by MoEF
- Plant Quarantine Order, 2004 by NBPGR under MoA
- Seed Policy, 2002 under MoA
- DGFT Notification Relating to Inclusion of GM Policy in Foreign Trade Policy (2006-09) by MoC&I
- Food Standards and Safety Act, 2006 by MoH&FW
- Drugs and Cosmetics Amendment Act, 1972 by MoH&FW

Coverage of Rules 1989

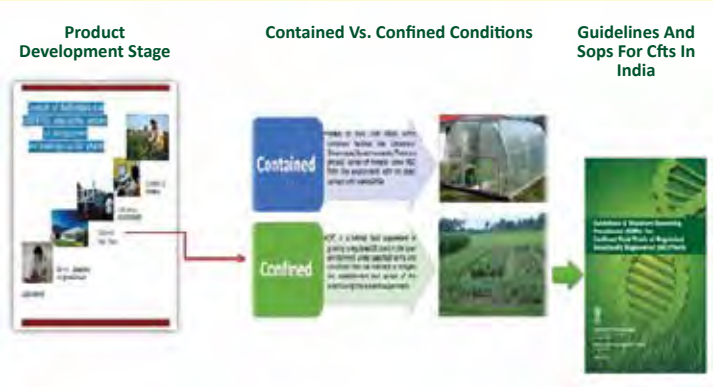
- All activities involving research and development of products containing GMOs/HMOs including transgenic crops, pharma products, industrial products, food and foodstuffs.
- Field trials /clinical trials
- Deliberate/unintentional release
- Import/Export/ Manufacture

Statutory Bodies

- Recombinant DNA Advisory Committee (RDAC) — Advisory
- Institutional Biosafety Committee (IBSC)
- Review Committee on Genetic Manipulation (RCGM) — Approval
- Genetic Engineering Appraisal Committee (GEAC)
- State Biotechnology Coordination Committee (SBCC) — Monitoring
- District Level Committee (DLC)



Stages of Development of a GE Crop



Biosafety Guidelines for GE Crops

- Recombinant Dna Safety Guidelines, 1990
- Revised Biosafety Guidelines, 1994
- Revised Guidelines For Research In Transgenic Plants, 1998
- **Guidelines And Standard Operating Procedures (Sops) For The Conduct Of Confined Field Trials Of Regulated, Genetically Engineered Plants In India, 2008**
- Guidelines For The Safety Assessment Of Foods Derived From Genetically Engineered Plants In India, 2008

Procedure for Approval for Field Trials and Environmental Release of Transgenic Crops

Institutional Biosafety Committee (IBSC)
(forwarding applications for approval of RCGM)

Review Committee on Genetic Manipulation (RCGM)
(green house experiments, contained field trials i.e. in-house trials/initial hybrid trials, generation of data on gene stability and expression, biosafety data

↓

RCGM
[approval for conduct of event selection and BRL-I field trials /Seed production on the selected varieties) /hybrids)] and biosafety data

↓

Evaluation of field trials – Compliance Monitoring Committee.

↓

Genetic Engineering Appraisl Committee (GEAC)

↓

BRL-II ← **Seed Production** → Seed Production

↓

Compliance Monitoring

↓

GEAC
(Review of safety of the event/gene in a given background)

↓

Stakeholders Consultations

↓

Review

↓

Material cleared from Environmental angle by MoEF/or otherwise

Information/data requirements for the safety assessment of GE plants during CFTs

	Food & Feed Safety Assessment		Environmental Risk Assessment	
	Field studies	Non-field studies*	Field studies	Non-field studies*
Acute oral safety limit study				
Pepsin digestibility assay				
Protein thermal stability				
Subchronic feeding study in rodents (if required)				
Livestock feeding study (if required)				
Molecular characterization				
Inheritance of introduced trait				
Stability of introduced trait				
Expression of introduced protein(s)				
Compositional analysis				
Reproductive and survival biology				
Impact on non-target organisms: Tier I testing				
Impact on non-target organisms: Tier 2 testing				
*Run concurrently with field trials				

Types of Field trials

- Event selection Trials
- Biosafety Research Level-1 Trials
- Biosafety Research Level-2 Trials
- Experimental seed production Trials
- Trials for production of plant material
- Trials for specific environmental safety studies

Regulatory Process for CFTs

- The initial assessment of an application for confined field trial begins at the institutional level itself.
- Based on information generated by the applicant in lab/greenhouse and **on preliminary phenotypic evaluation of event selection,** an application is made to IBSC for one to a few events for further evaluation.
- If recommended by IBSC the applicant may submit an application to RCGM for biosafety assessment of the event along with necessary requirements.
- RCGM is the regulatory authority for Biosafety Research Level I (BRLI) trials. These trials are limited to no more than one acre per trial site location.

Regulatory Process

- GEAC is the regulatory authority for Biosafety Research Level II.(BRL II) trials. Size and number of trials will depend on case by case.
- GEAC approval is subject to NOC from State Governments.
- Minimum of three seasons/years BRL trials are required for generating biosafety data for an even

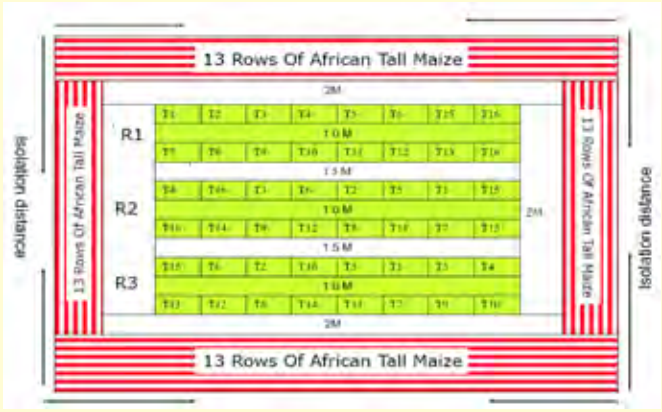
	Option 1:	**Option 2:**
Year/season I	BRL I	BRL I
Year/season II	BRL I	BRL II
Year/season III	BRL II	BRL II

Precautions during field trials

- Maintaining a crop specific isolation distance from the periphery of the experimental site to other sexually compatible crop fields as prescribed under the Indian Minimum Seed Certification Standards.
- Maintaining biological and physical barrier around the experimental plot
- Submission of a validated event specific test protocol of 0.01% before undertaking the trials.
- Designating a lead scientist who would be responsible for conducting the trial. Event Selection trials and BRL-1 trials for new events are not permitted in the farmers' field.
- Post harvest restrictions include (a) burning of the border rows and left over plants and plant parts from the entire experimental plot; (b) the trials sites should not be used for planting the same plant species and (c) the site should be monitored for volunteers and rendered non-viable before flowering.

Biology Documents

Regulatory Process



GM Crops Field Trials

Fence, Border rows and notice boards

GM Crops Field Trials


Roundup spraying

Research Activities


Harvest & Destruction


DLC Members during destruction of plant

Why are CFTs regulated?

To ensure that all science based precautions are undertaken to restrict the movement of regulated GE plant within the confinement of trial site at all stages of field trial as well as post harvest /termination phase.

To strengthen methodical evaluation of GE Plant

How is safe conduct of CFT ensured ?

1. **Compliance of Guidelines for Conduct of CFT Components**
   - Guidelines for conduct of field trials
   - Application form
   - Standard Operating Procedures
   - Recording formats
   - Guidelines for monitoring of CFTs
   - Glossary of terms
2. **Monitoring of CFT**

   Regulatory agencies authorized to monitor/ inspect field trials include RCGM/GEAC/SBCC/DLC and monitoring teams set up RCGM/ GEAC.

Main Components of CFT Guidelines

1. **Introduction**
2. **Contained vs. Confined Conditions**
3. **Regulatory Authorities**
4. **Scope**
5. **Terminology**
6. **Application and Authorization/Approval**
7. **General Requirements**

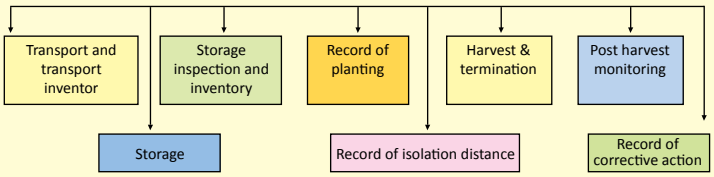
SOPs for Conduct of CFTs

1. SOPs have been prepared to provide guidance for the following aspects of conducting CFT of GE crops
   - Transport of GE material
   - Storage of GE material
   - Management of trial
   - Harvest and termination of trial
   - Post harvest management and land use restriction
2. Each SOP has a recording format for documentation.

Recording Formats

All the relevant records are to be filled as per the requirements indicated in each SOP.

Following records in the formats are required to be maintained.



Guidelines for Monitoring of CFTs of GE Plants

To provide guidance to designated members of monitoring teams who have been given responsibility of determining whether the **conduct of a confined field trial,** including the condition of the trial site, or storage facility, and availability of relevant documentation and records, are in compliance with the terms and conditions of permit.

Inspection by Central Compliance Committee (constituted by Department of Biotechnology/MoEF&CC)

- Expert scientist (Chairman)
- Scientists from concerned SAUs
- Officials of State Department of Agriculture
- RCGM Nominee
- GEAC Nominee

Information on Biosafety regulations may be viewed at www.envfor.nic.in, www.igmoris.nic.in

Thank You

2.2 Monitoring Confined Field Trials of Regulated GE Plants

Introduction

What Are Confined Field Trials (CFTs)?

- Part of the research process
- Carefully controlled
- Small-scale

Scale of CFTs

Contained Use Laboratory or Greenhouse experiments	**Confined Use** Small-scale isolated Experimental field trials	**Unconfined Use** Farm-scale evaluations Farmers fields
		
Pots or trays	1-2 acres	84 million acres
100s of plants	30,000 plants/acre	2.52 x 1012 plants

Why Are CFTs Performed?

- Evaluate agronomic performance
- Collect data on potential ecological and biosafety impacts
- Weedy characteristics
- Environmental fate of novel plant-expressed proteins
- Impacts on beneficial, endangered, or other organisms
- Generate plant tissue for nutritional analyses, novel protein expression studies, and feeding studies

Ensuring Safe Conduct of CFTs

CFTs involve the use of plants for which the potential environmental impacts are not completely known.

- Establish CFT management guidelines
- Impose permit conditions ("conditions of authorization")
- Monitor performance

The role of the monitor is essential to the effective regulation of CFTs, and both internal and external monitoring help ensure that no adverse environmental impacts occur.

2.3 Assessment and Management of Risks Posed by Confined Field Trials

Risk Assessment

Risk assessment is a science-based process

- It identifies hazards, relative to a particular valued resource.
- It assesses their magnitude (severity) and duration.
- It estimates the likelihood of the hazard occurring.

Environmental Risk

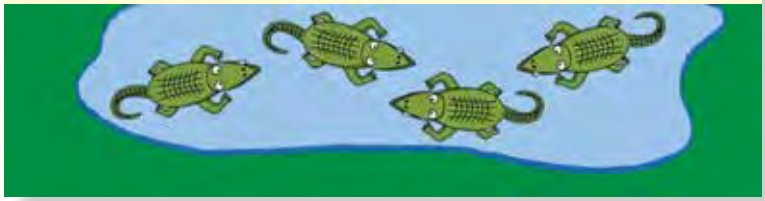
- The probability that something bad will happen to a valued environmental resource
- Determined by the nature of the hazard and the amount of exposure to the hazard

  Risk = f(hazard • exposure)
- Both hazard and exposure contribute to the risk

Risk Characterization: Example 1

Resource: Lake for swimming

Hazard: Alligators



Risk = f(hazard • exposure)

Hazard is very high for a swimmer encountering an alligator.

What exposure results in acceptable risk?

Risk Characterization: Example 2

Resource: Lake for swimming

Hazard: Goldfish

Risk = f(hazard • exposure)

Hazard is very low for a swimmer encountering an goldfish.

What exposure results in acceptable risk?

Risk Characterization Matrix

		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			

After considering all the available, relevant information, risk assessors need to make a decision regarding the risk posed by the CFT of a particular GE plant.

Example: Drought Tolerant Maize

- Environmental Resource: Native plant species
- Hazard: Displacement of drought- sensitive native plant species by DT maize
- Exposure: Frequency of DT maize escape from cultivation and establishment in native habitats

Effect of Exposure on Risk

- With unconfined (commercial) release, any farmer can buy and plant the seed.
- There is no attempt to limit the exposure.
- Acceptable risk is controlled by making sure that there is negligible hazard associated with the crop.

Acceptable Risk = f(hazard • exposure)

Effect of Exposure on Risk

- In the case of research, the nature of the hazard posed by the GE plant may not be fully known.
- Risk is controlled by minimizing exposure.
- The GE plant is contained or confined so that the environment is not exposed to the plant in ways that will allow a particular hazard to be realized.

Acceptable Risk = f (hazard • exposure)

Risk Characterization Matrix

		Risk Characterization			
CFTs → 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			

General Release ↑

Group Exercise 1 – Assessment and Management of Risks Posed by Confined Field Trials

	Hazard	Exposure	Management Options	Management Effectiveness	Management Cost
Polar bear attack					
Skin cancer from sunlight					
Loss of hearing from environmental noise					
Catching a cold					
Automobile accident					
Computer virus					
Getting polio					

2.4 Risk Management Methods for Confined Field Trials

Once the IBSC and RCGM or GEAC review a CFT application, and the decision is made that the CFT can be permitted, it still has to be determined how it will be permitted.

Risk Management Methods for Confined Field Trials

There are three broad principles that are followed to conduct the CFT safely

- Prevent dissemination of new genes in experimental transgenic plant into and within the environment (i.e. prevent pollen-mediated gene flow).
- Prevent the persistence in the environment of the experimental transgenic plant and any progeny plants.
- Prevent the introduction of the experimental transgenic plant (or products) into the livestock feed and human food pathways (commingling).

CFT Permit Conditions

- The regulators impose a combination of general and case-specific conditions that the Permitted Party must comply with.
- These Conditions of Authorization are listed in the authorization letter to the applicant.
- The purpose of these conditions is to manage any unknown hazards that may be posed by the GE crop/trait combination.

CFT Permit Conditions

Depending on the circumstances, there may be one or more conditions imposed for every stage in 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

CFT Permit Conditions

Permit conditions are imposed to manage risks by preventing undesirable outcomes from the CFT:

- Pollen from experimental GE plants pollinating nearby crops or wild plant species
- Experimental GE plants escaping from the trial site
- Experimental GE plants persisting in the environment
- Experimental GE plant material becoming commingled with non-GE material
- Experimental GE plant material entering the food/feed supply

Preventing Unwanted Pollination

Central to the management of the CFT is the reproductive isolation of the GE plant.

- Prevents the GE plant from pollinating nearby, sexually compatible plants
- Several different techniques exist
- Techniques can be used individually or in combination

These techniques are commonly used by plant breeders to produce certified seed.

Preventing Escape and Persistence

Permit conditions will focus on reducing the chance that the GE plants in the CFT will escape into the environment.

- All propagable GE plant material must be destroyed at the trial site, unless the Permitted Party has permission to remove material.
- Volunteer plants at or near the CFT site must be destroyed before they flower.

Preventing Commingling

Additional conditions will be imposed to ensure that the GE plant material will not enter the food and feed supply.

- 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
- Controlling the disposition of any material retained after harvest, such as seed that is saved for subsequent analyses

Effective Risk Management

Risk management is used to further reduce the already low risks from CFTs. But effective risk management requires

- Appropriate techniques
- Well-trained field workers
- Committed Trial In-charge (TIC)
- Sufficient resources
- Internal and external monitoring

Group Exercise 2 – Risk Management Methods for Confined Field Trials

Crop	Characteristics	Confinement Challenges (when?)	Confinement Management (when?)
Maize			
Cotton			
Rice			
Bean			
Banana			

2.5 Transportation and Storage of Regulated GE Plant Material

SOPs for Transportation and Storage

Goals of these guidelines

- Prevent the accidental loss of GE material
- Prevent commingling GE material with non-GE
- Facilitate corrective actions, when necessary

Container Requirements for Transport

- Primary and secondary containers must be used
- Containers must resist breakage and leakage
- Separate primary containers must be used for each event.
- Non-GE material must also be in separate primary containers
- Containers may be re-used after cleaning; devitalize any GE material collected after cleaning

Container Labels

- Each primary and secondary container will be labeled.
- Primary container labels will indicate the ID number or variety name of the contents.
- Secondary labels will have emergency contact information for the Transport In-charge and the Receiver.

Transport Documentation

Record of Transport (RoT)

- Transport In-charge completes pre-transport sections of RoT.
- If there are multiple primary containers within one secondary container, the Transport In-charge prepares a Transport Inventory List.
- A copy of the RoT and the Inventory List is sent to the Receiver before the package is shipped.
- The original RoT and the Inventory List is placed in the secondary container, and the Transport In-charge retains copies.

Receipt of Shipment

- Inspect containers for breakage or leakage.
- Confirm all paperwork is present in the secondary container; request any documents from the Transport In-charge.
- Receiver will complete the RoT and send a copy to the Transport In-charge.

Corrective Actions

Any non-conformities should be communicated to the Transport In-charge within 24 hours

- Any shipment with missing or inconsistent paperwork should be shelved until the paperwork arrives.
- Leaking/broken containers must be inspected/weighed to determine what is missing and how much.
- Any spilled material must be recovered and retained using appropriate containers, or devitalized.
- If the secondary container has leaked, mark the area; if outdoors, the area must be monitored.
- Document all actions in a Record of Corrective Action (RoCA); Receiver retains original, and a copy is sent to the Transport In-charge, Permitted Party, and RCGM/GEAC.

Storage Facility Requirements

- The Permitted Party/Facility In-charge (FIC) is responsible for the storage facility.
- The storage facility must be
- A fully enclosed space
- Locked, with limited access by authorized personnel
- Labeled
- Inspected monthly by FIC
- An up-to-date facility Record of Storage and Record of Storage Inspection must be kept by the FIC. The inventory should record the current contents of storage facility and additions to and removals from the facility.

Corrective Actions

Any non-conformities should be communicated to the Transport In-charge within 24 hours

- Leaking/broken containers must be inspected/weighed to determine what is missing and how much.
- Any spilled material must be recovered and retained using appropriate containers, or devitalized.
- If a spill occurs, mark the area; if outdoors, the area must be monitored.
- Document all actions in a Record of Corrective Action (RoCA); Receiver retains original, and a copy is sent to the Transport In-charge, Permitted Party, and RCGM/GEAC.

Storage Facility 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.

GROUP EXERCISE 3 – TRANSPORTATION AND STORAGE OF REGULATED GE PLANT MATERIALS

For the following three scenarios, list the containment issues that are raised and propose appropriate storage or transport measures that comply with the guidelines, including monitoring and reporting requirements.

Scenario A: A researcher is conducting experiments to develop GE sweet potato varieties. Her lab creates transgenic plants throughout the year, but she only has access to a greenhouse for six months each year, so she needs to store the GM potatoes until she is allowed to use the greenhouse. Her laboratory has a walk-in refrigerator that would provide year-round storage conditions for these potatoes as well as non-GM research materials.

Scenario B: A researcher will use cultured cells of cassava in his work to develop transgenic cassava plants. He intends to store transgenic cell lines in liquid nitrogen, using a liquid nitrogen storage tank that is maintained by his department and shared by all researchers.

Scenario C: A university researcher has developed several GM banana varieties. He is using a greenhouse to grow small banana plantlets in pots. A colleague at another university has requested ten of these plants to grow in an enclosed growth chamber at her university. The plantlets are 25 cm tall, and they must be shipped with soil around the roots.

2.6 Planting and Maintaining the Confined Field Trial

Planting and Maintaining the CFT

- Equipment must be cleaned of GE plant material before it leaves the CFT site.
- The Trial In-charge (TIC) must prepare and maintain the trial map.
- The TIC must complete the Record of Planting (RoP) and send a copy to RCGM/GEAC within 7 days of planting; TIC retains the original.
- The TIC must maintain a notice board at the CFT site.

Planting and Maintaining the CFT

- The corners of the site must be marked throughout the trial and post-trial monitoring.
- Any plant material removed should be devitalized on site or transported (if permitted) using approved containers.
- Access to the site is by authorized personnel only; all site visits will be recorded.

Maintaining Reproductive Isolation

- The TIC must implement the Reproductive Isolation methods as described in the authorization letter.
- The TIC must monitor the CFT site at least every 2 weeks from planting through harvest, and ensure that prohibited plants are removed and destroyed before they flower.
- Reproductive Isolation must be implemented continuously around the CFT.
- All activities must be recorded in the **Record of Reproductive Isolation** (RoRI).

CFT Record keeping

- All records must be maintained through the post- harvest management period.
- After post-harvest period, the TIC will forward all records to the Permitted Party.
- The Permitted Party will retain the records (RoP, RoRI, and RoCA) for a period of 5 years.

Corrective Actions

Any non-conformities should be communicated to the Transport In-charge within 24 hours

- Any spilled material must be recovered and retained using appropriate containers, or devitalized.
- If a spill occurs, mark the area; if outside the boundaries of the CFT site, the area must be monitored.
- Document all actions in a Record of Corrective Action (RoCA); TIC retains original, and a copy is sent to the Permitted Party and RCGM/GEAC.

CFT Trial Site Map

Requirements

- Good maps of the trial site are crucial, both for the management of the CFT and for monitoring.
- Part of the application process
- Supplement **the Record of Planting**
- Document specific crop management events, like pesticide applications
- Because the map tells the history and future of the trial, it may be necessary to produce several maps.
- Because of the importance of the trial site map in the risk management of the CFT, the map must meet several requirements.

CFT Trial Site Map

Requirements

- Maps of confined field trials must be **legible and precise.**
- A map of the trial site will be prepared by the TIC and appended to the Record of Planting.
- Maps must provide sufficient detail to allow regulatory officials to **locate each field trial site** from planting through any period of post-harvest land use restriction.
- Maps must provide details on the **layout** of the site and **distances** between the field trial site and surrounding features.
- The dimensions of the trial site and distances to physical landmarks must be **accurately reported.**

CFT Trial Site Map

Requirements

- TIC's name and contact details
- Permit number from the regulatory authority
- Legal or descriptive land location (name of the village, taluka, district, state)
- Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.
- Total area planted with the regulated material, including negative controls and any border or guard rows when used (acres or square meters)

CFT Trial Site Map

Requirements

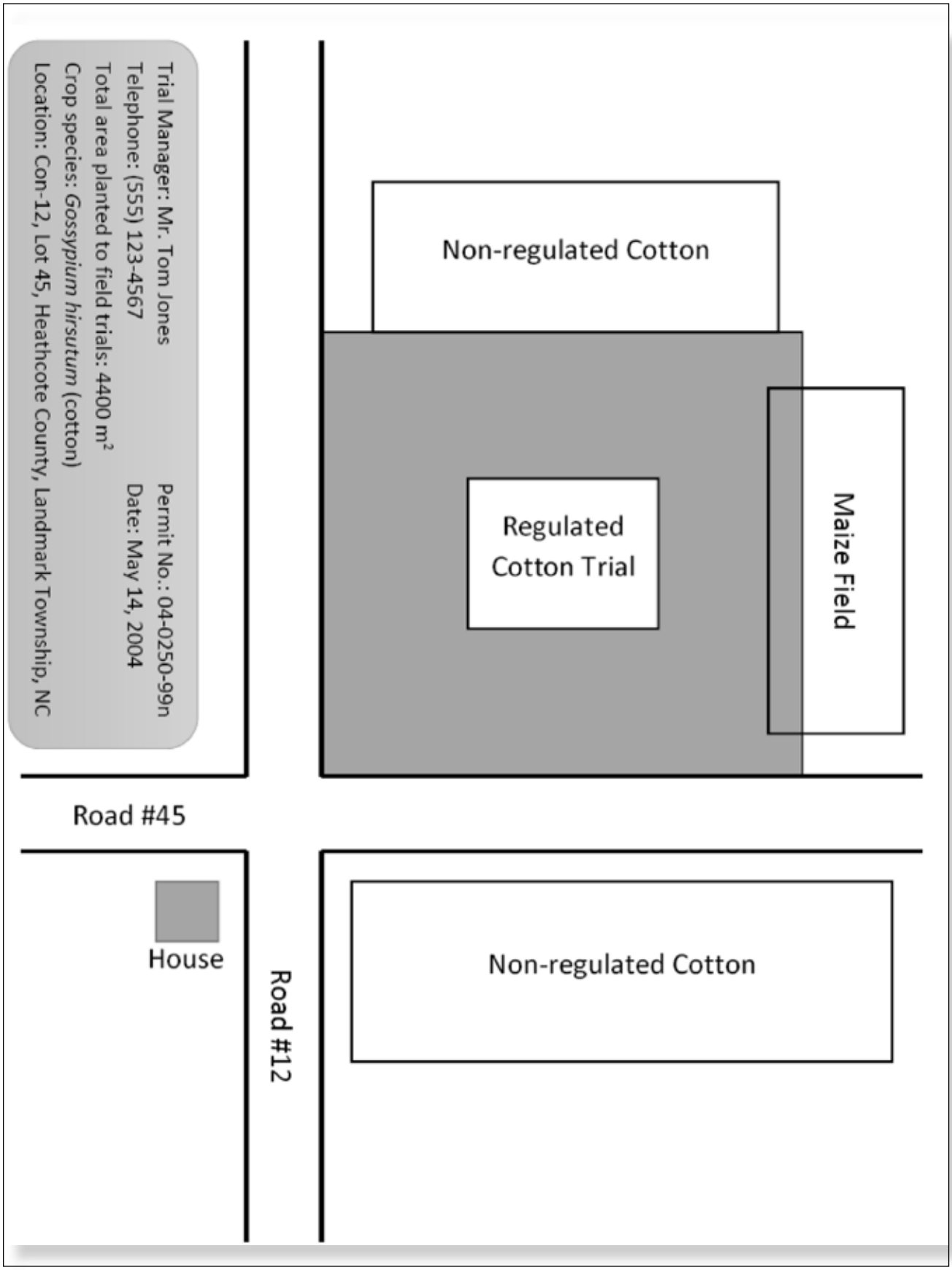
- Labels on all fields within the isolation area by the common name of the crop.
- Indication of any fields of same/related crops that fall within, or border on, the isolation area.
- Identification of any natural ecosystems adjacent to the trial site (natural habitats, waterways, gardens, orchards, forests, and woodlots, hedgerows), wherever reasonable.
- Planting date
- Compass directions, with North at the top of the page

GROUP EXERCISE 4 – PLANTING AND MAINTAINING THE CONFINED FIELD TRIAL

Exercise A. You are in the process of inspecting a confined field trial for GM cotton. The Trial In-Charge has provided you with the attached map of the field trial site. Review the map and indicate on the map any information that is missing. In the space below, explain why this missing information is important to the proper management of risks from the trial.

Exercise B. Each crop may pose different challenges to the Trial In-Charge when trying to meet the various requirements for managing a confined field trial. In the table below, think about the biology of the crops provided, and list the challenges that may be encountered meeting the specific requirements when conducting a field trial with that crop. Then suggest measures that may help the Trial In-Charge ensure effective reproductive isolation of the crop.

Crop Compliance	Requirement	Challenges and Suggestions
Tobacco	C.2.1.	
Mustard	C.3.2.	
Radish	C.3.6.	
Rice	C.6.1.	


Trial Manager: Mr. Tom Jones
Telephone: (555) 123-4567
Total area planted to field trials: 4400 m²
Crop species: Gossypium hirsutum (cotton)
Location: Con-12, Lot 45, Heathcote County, Landmark Township, NC
Permit No.: 04-0250-99n
Date: May 14, 2004
Non-regulated Cotton
Regulated Cotton Trial
Maize Field
Road #45
House
Road #12
Non-regulated Cotton

2.7 Reproductive Isolation

Pollination

For one plant to pollinate another plant, several things all have to happen:

- The plants must be at least partially sexually compatible.
- The male parent must be shedding pollen when the female parent is receptive to pollen.
- The pollen must be successfully carried, by wind or a pollinator, from the male parent to the female parent.

Reproductive Isolation

Reproductive Isolation comprises various techniques that prevent the GE plant from pollinating sexually compatible plants that are in the vicinity of the CFT, including both cultivated and wild plant species.

Reproductive Isolation techniques are commonly used by plant breeders to reduce unwanted pollination when producing certified seed.

Implementing Reproductive Isolation

Reproductive Isolation is the central risk management tool for CFTs.

- Reproductive Isolation must be fully understood by the TIC
- How the various techniques work
- How the various techniques can fail
- Reproductive Isolation must be used effectively and consistently
- Reproductive Isolation must be verified through internal and external monitoring

Implementing Reproductive Isolation

The chosen method or methods must be used completely surrounding the trial site, regardless of the landscape and weather pattern.

One method may be sufficient, but backup isolation methods may be used.

Monitoring is essential.

Spatial Isolation

Plant breeders have known for generations that if two plant populations of the same species are

kept far enough apart, the chance of cross pollination falls to zero.

Spatial Isolation

The effective distance for spatial isolation is species specific and depends on reproductive biology:

- Is the plant self-pollinated, wind pollinated, or pollinated by an animal?
- How long is the pollen viable?
- What is the foraging range of the pollinator (bee, bird, bat)?

Brinjal

Implementing Spatial Isolation

- The isolation distance must be kept completely free of other plants of the same species, or plants sexually compatible with the GE plant.
- Prohibited plants must be removed before they flower.
- If prohibited plants are allowed to flower, reproductive isolation has been breached, and the Permitted Party will become responsible for the entire isolation zone, and must treat it as if it were part of the CFT.

Temporal Isolation

Different crop varieties are known to flower at different times. It is possible to stagger planting times so that the GE crop flowers many days before or many days after any plants near enough to be within the spatial isolation distance.

Sugar Beet

Implementing Temporal Isolation

- The flowering time of the GE crop variety must be significantly earlier or later than plants in neighboring fields.
- The CFT and any neighboring fields of the same crop must be rigorously monitored to verify that the two fields are not in flower at the same time.
- If the CFT and a neighboring field of the same crop are in flower at the same time, then there has been a breach of reproductive isolation.

Removal of Floral Structure

Removing the male flowers or male flower parts from the GE plant will make it impossible for cross pollination to occur.

Implementing Flower Removal

- Frequent and rigorous monitoring for developing flowers must occur. The frequency should increase as flowering time approaches.
- Flower removal must be timely and complete. Field workers must be properly trained.
- Remember, removed plant material must be properly devitalized, unless the Permitted Party has permission to remove the material from the site.
- If male flower parts are present when nearby fields of the same crop are in flower, then there has been a breach of reproductive isolation.

Bagging of Floral Structure

Plant breeders routinely place paper bugs over flowers or floral parts to restrict pollen movement. In most respects, it is similar to removing flower parts.

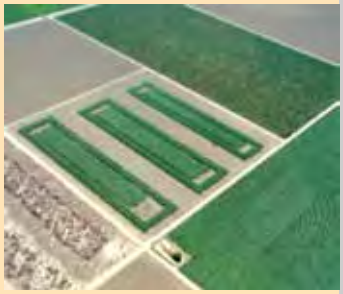
Rice

Implementing Flower Bagging

- Frequent and rigorous monitoring for developing flowers must occur. The frequency should increase as flowering time approaches.
- Flower bagging must be timely and complete. Field workers must be properly trained.
- After bagging has occurred, monitoring must continue to ensure that bags are not dislodged by wind.
- If male flower parts are exposed when nearby fields of the same crop are in flower, then there has been a breach of reproductive isolation.

Pollen Trap Rows

In this technique, several rows of non-GE plants of the same species are planted around the CFT. These plants attract pollinators that may have collected pollen from flowers in the CFT, so that the pollinators do not cross pollinate plants in nearby fields.



Cotton

Implementing Pollen Trap Rows

- This technique works only with some insect-pollinated crops, like cotton.
- The variety used in the trap rows must flower at the same time as the variety in the CFT, and for the same length of time or longer.
- The trap row plants should be planted at the same density as the plants in the CFT.
- The trap rows must be monitored to ensure that the plants are healthy.
- The TIC must exercise caution if the GE plants are herbicide tolerant and herbicides will be applied.

Early Termination

With this approach, all of the plants in the CFT are simply destroyed before they flower.

Cabbage

Implementing Early Termination

- The CFT must be carefully monitored so that the termination can be timed properly.
- All plant material must be devitalized at the CFT site.
- Early termination does not relieve the Permitted Party from post-termination monitoring.

Monitoring Reproductive Isolation

- No Reproductive Isolation method works automatically.
- Each Reproductive Isolation method requires consistent, rigorous, timely monitoring to be effective.
- Growth stage of crop
- Prohibited plants in isolation zone
- Thoroughness of bagging, flower removal
- Routine monitoring should be recorded, including date of monitoring and any unusual circumstances that might impact the effectiveness of isolation.
- Inadequate monitoring could result in the breach of Reproductive Isolation and termination of the trial.

GROUP EXERCISE 5 – REPRODUCTIVE ISOLATION METHODS

Although there are several effective reproductive isolation methods, not all of them work well with all crops. In the table below, you have been given several combinations of crops and reproductive isolation methods. Indicate in the right column the challenges facing the Trial In-Charge to effectively implement reproductive isolation. Then suggest measures that may help the Trial In-Charge ensure effective reproductive isolation of the crop.

Crop	Reproductive Isolation Method	Implementation Challenges and Suggestions
Maize	Flower structure removal	
Cotton	Pollen trap rows	
Mustard	Temporal isolation	
Rice	Flower bagging	
Sorghum	Spatial isolation	Inspecting isolation zone for volunteers or non-GE sorghum plantings

2.8 Harvest and Disposition of Regulated GE Plant Material

SOPs for Harvest and Termination

- Clean all equipment before removing it from CFT site.
- Any GE plant material not retained must be rendered non-viable.
- Animals must not be allowed to graze at the CFT site.
- The TIC should monitor all activities and record all relevant information in the Record of Harvest/Termination (RoHT).

Transport of Materials Offsite

- Follow the same procedures as for other transport.
- Use approved containers for all materials.
- Specialized containers may be necessary for some materials, and these should be cleared with RCGM/GEAC.

Corrective Actions

Any non-conformities should be communicated to the Transport In-charge within 24 hours

- Recover as much materials as possible.
- Record the nature of the incident and the details of the response in the RoCA.
- Contact RCGM/GEAC within 24 hours.
- Mark areas where any spillage occurs and establish a monitoring process to ensure that no further release occurs.

Records

Copies of the completed RoHT should be sent to the Permitted Party and to RCGM/GEAC within 15 days of harvest/termination.

Post-Harvest Management

- The focus of post-harvest management is monitoring for volunteers from the CFT and any other signs that an accidental release may have occurred.
- The terms of post-harvest management are crop specific and will determined by the regulators.

Implementing Post-Harvest Management

- The Permitted Party must have written permission to access to the site throughout the post-harvest monitoring period.
- Only the trial site itself is subject to post-harvest monitoring, unless there was a breach of Reproductive Isolation during the course of the trial.
- Monitor trial at least once every 4 weeks.
- Identify, remove, and destroy any prohibited plants.
- Record all monitoring activities.
- Do not allow the site to be planted with the same crop as was grown for the CFT, until the monitoring is completed.

Corrective Actions

Any non-conformities should be communicated to the Transport In-charge within 24 hours

- Recover as much materials as possible.
- Record the nature of the incident and the details of the response in the RoCA.
- Contact RCGM/GEAC within 24 hours.
- Mark areas where any spillage occurs and establish a monitoring process to ensure that no further release occurs.

Records

Copies of the completed **Record of Post- Harvest Inspection** should be sent to the Permitted Party at the conclusion of the post-harvest period.

GROUP EXERCISE 6 – HARVEST AND DISPOSITION OF REGULATED GE PLANT MATERIAL

Each crop may pose different challenges to the Trial In-Charge when trying to meet the various requirements for harvesting a confined field trial. In the table below, think about the biology of the crops provided, and list the challenges that may be encountered meeting the specific requirements when conducting a field trial with that crop. Then suggest measures that may help the Trial In-Charge ensure effective confinement of the crop.

Crop	Requirement	Challenges
Tobacco	D.2.2.	
Sweet Potato	D.3.1.	
Banana	E.3.5.	
Rice	E.4.1.	

2.9 Introduction to the Monitoring of CFTs

To Review

CFTs involve the testing of experimental GE plants that have not yet been completely characterized. Some residual risks may exist.

These risks are managed by keeping CFTs very small and by putting in place a system of controls, both physical and biological, that will keep the GE plants confined to the trial site and prevent their persistence in the environment and introduction into the food supply.

Monitoring Is Crucial

Risk management will only work when all the **permit conditions** are met correctly and all the controls are in place to **ensure confinement.**

Therefore, the safety of CFTs relies on **effective, rigorous internal and external monitoring** to verify that CFTs are operated in compliance with all applicable regulations and guidelines.

Terms of Reference for Monitors

Monitors have been delegated authority under the Rules 1989 to inspect contained storage facilities for regulated GE plant materials and CFTs. Monitors receive a letter of authorization and a copy is sent to the Permitted Party. The letter must be presented to the TIC or FICduring the site visit.

Terms of Reference for Monitors

The team should communicate with the Permitted Party in advance of the visit to describe the **scope of the visit, request documents** and records that should be available for inspection, and to **answer any questions** from the Permitted Party.

Monitoring teams typically do not make "surprise" visits. The TIC or FIC may accompany the monitoring team during the visit.

Guidelines for Monitor Behavior

Ethical Conduct

- Monitors shall conduct themselves in a **professional, ethical** manner.
- All information reviewed or collected during the visit shall be considered **confidential.**

Guidelines for Monitor Behavior

Fair Presentation

- Observations and other information collected during the visit will be accurately recorded in the monitoring report.
- Divergent views should be recorded in the monitoring report.

Guidelines for Monitor Behavior

Due Professional Care

- The monitoring team will exercise care during the inspection.
- The team leader will be responsible for ensuring that the team has the necessary expertise to complete the inspection.

Guidelines for Monitor Behavior

Independence

- Monitors should not have any **bias** or conflicts of interest regarding the inspection.
- Monitors must remain **objective** and base their report on facts.

Guidelines for Monitor Behavior

Evidence-Based Approach

- Conclusions in the report must be based on evidence.
- Impressions, recommendations, and other notes, not related to a regulatory action, may be included in the report.

Authorized Role of the Team

The monitoring team acts under theauthority of the DBT. Its responsibilities are limited to:

- determining whether prescribed risk management measures are being implemented correctly, consistently, and effectively
- accurately recording evidence regarding potential lapses in risk management to provide regulators with sufficient information to determine if regulations have been violated

Authorized Role of the Team

- 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 DBT

Activities Outside the Authorized Role

- 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 Permitted Party, Facility In-charge, or Trial In- charge.

Activities Outside the Authorized Role

- The overall experimental design and specific experimental protocols used to collect data have already been reviewed by RCGM, 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.

GROUP EXERCISE 7 – INTRODUCTION TO MONITORING OF CONFINED FIELD TRIALS

Over the course of a confined field trial, there are several key stages when crucial activities are taking place, and a monitoring team may be called in specifically to observe these activities.

- Pre-planting
- Planting
- Anthesis
- Harvest
- Post-harvest, including termination and post-ter mination activities

Monitoring is always a valuable practice, at any stage of the CFT, but certain factors, such as the crop that is being tested, suggest specific times when monitoring will be especially useful. For the following crops, consider their reproductive biology and other characteristics and suggest which of the above stages in the course of a CFT should be the focus of monitoring activity, if only one or two monitoring visits was possible. Please explain your choices.

1. Maize

2. Common bean

3. Cotton

4. Banana

2.10 Monitoring Process

Planning the Site Visit

Each CFT poses slightly different risk management challenges, due to

- Crop
- Engineered trait
- Size of the CFT
- Location of the CFT

Monitoring should be tailored to the specific circumstances of each trial.

Planning the Site Visit

Whenever the visit occurs, the team should be looking into the past and the future, as well as the present status of the trial

- Is there evidence that risk management measures were not effectively used in the past?
- Could some current practices lead to a compliance failure in the future?

Preparation for the Site

The team should review the following documents before visiting the site:

- 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
- The trial site map
- Prior monitoring reports (ask the Permitted Party)

Preparation for the Site Visit

The team should discuss how the visit will proceed.

- What factors will merit the most attention?
- Which records should be reviewed in detail?
- For a CFT, what challenges will the crop pose for Reproductive Isolation?
- Which records should be reviewed in detail?

Guidelines for Monitor Behavior

The team leader should contact the PP/TIC/FIC to schedule the site visit.

- Contact the Members of Monitoring team (CCC) through PP/TIC.
- Discuss which activities will be observed
- Request documents to be ready for review
- Determine where and when the visit will take place, and estimate how long the visit will last
- Answer any questions from the PP/TIC/FIC

Preparation for the Site Visit

The team should consider bringing the following items to collect and record information:

- Checklists, monitoring forms, notebook
- Measuring tape
- Digital camera
- Sampling containers

Conducting the Site Visit

The team should consider relevant evidence to verify effective risk management:

- 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

Conducting the Site Visit

- 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

Document Inspection

Documentation should be complete, correct, and compliant with regulations.

- Letter of permit authorizing conduct of the confined field trial
- All required notices (Planting, Harvest, Accidental Release)
- Record of Transport for shipments of regulated plant material to, and between, field trial sites and contained facilities
- Record of Storage and Record of Storage Inspection
- Record of Planting and Record of Spatial Isolation and/or records for other methods of reproductive isolation
- Record of Harvest/Termination and Disposition
- Record of Post-Harvest Inspection
- Record of Corrective Action

Document Inspection

If this is not the first visit, review past monitoring reports (ask Permitted Party) for past problems with documents. Note if problems have been resolved.

Storage Facility Inspection

The monitoring team should ask the FIC to have the following documents available for review:

- Shipping or courier records associated with movement of the regulated plant material
- Types and quantities of regulated plant material that are stored at the facility
- Locations associated with any recent movements (origin, intermediate, and final destination) and the dates of these movements
- Containment requirements specific to the facility, building, or location to be inspected

Storage Facility Inspection

The monitoring team should ask the FIC to have the following documents available for review:

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

Storage Facility Inspection

The monitoring team should verify that the facility meets the guideline standards:

- Regulated plant material is appropriately labelled and stored separately from any conventional seed or plant material in a fully enclosed, lockable space
- Regulated plant material is stored in appropriately labeled containers that will prevent the inadvertent release or loss of the material
- Storage facilities are checked at least once every four weeks to ensure they are secure and clean and that material packaging or labelling has not been compromised, and this activity should be documented on records of storage inspection completed

Storage Facility Inspection

- The storage area is clearly marked as containing regulated plant material, and used exclusively for that purpose
- All regulated plant material in storage is recorded on an inventory record, which also records all additions to, or removals from storage
- 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

Field Trial Site Inspection

The team should be familiar with the following:

- Crop species and GE trait
- Experimental design and purpose
- Confinement measures to be used
- Permit conditions imposed

Planning the Site Visit

Stages in the course of performing a CFT where there is an elevated risk of compromising confinement:

- Pre-planting
- Planting
- Pollination
- Harvest/Termination
- Post-Termination

Planning the Site Visit

- Pre-planting – trial site location and layout can make compliance more difficult
- Planting and Harvest – lots of activity, equipment use and cleaning, and more personnel on site can increase the chances of mishandling, spillage, and mislabeling

Planning the Site Visit

- Pollination – when gene flow can occur: a narrow window when all confinement measures must be in place and working properly
- Post-termination – last opportunity to verify that GE plants have not escaped the trial site

Site Location Considerations

Verify each of the following:

- Markers at all four corners of the field
- Field is the correct size
- Field layout matches the depiction in the trial site map

Spatial Isolation

Verify each of the following:

- Isolation distance is correct
- Isolation zone extends entirely around the trial site
- Isolation zone is free of prohibited plants
- Internal monitoring records show required monitoring was performed at the proper intervals

Temporal Isolation

Verify each of the following:

- Locations of sexually compatible crop fields are accurately shown on the site map
- The TIC is monitoring the flowering status of the GE plants and neighboring sexually compatible plants as required and keeping required records
- The GE plants and sexually compatible plants in neighboring fields are not flowering concurrently

Flower Bagging or Removal

Verify each of the following:

- Field workers were trained to perform bagging or removal process correctly
- Bagging or removal was done completely
- The TIC recorded dates when flowers were bagged or removed and when the field was monitored for early or late flowers

Pollen Trap Rows

Verify each of the following:

- Pollen trap plants are planted at the required distance and density
- Pollen trap plants are healthy
- Pollen trap plants are flowering at the same time as the GE plants
- The TIC is recording all monitoring activity performed on the pollen trap plants

Early Termination

Verify each of the following:

- The GE plants are being monitored regularly to ensure that they do not flower prematurely
- All GE plants are destroyed in the termination process
- The TIC is recording all monitoring activity of GE plant growth

Harvest/Termination and Disposition

The CFT may be either terminated early or it may be harvested and then terminated before the GE plant material is disposed of. In either case, the monitoring team should verify that the TIC has met the following requirements:

Harvest/Termination and Disposition

- Equipment and tools are cleaned of GE plant material before leaving the CFT site.
- Retained GE plant material must be transported in approved containers according to permit conditions.
- The Record of Harvest/Termination should completely document the harvest process and the final disposition of any residual GE plant material.

Post-Harvest Monitoring

At the end of the post-harvest monitoring period, the land on which the CFT was planted should be ready for non-restricted use. Therefore the goal of monitoring is to ensure that GE plants have not persisted on the land.

Post-Harvest Monitoring

Monitors should verify the following:

- The TIC is regularly monitoring the site to identify, remove, and devitalize any volunteers or prohibited plants.
- Trial site markers are being maintained.
- All post-harvest activities and monitoring have been recorded in the Record of Post-Harvest Monitoring. The records should confirm that all required monitoring has taken place.

GROUP EXERCISE 8 – MONITORING PROCESS

Below you will find three scenarios, describing observations made by a monitoring team during a visit to a CFT. For each scenario, answer two questions:

1. What is your reaction, as a monitor, to the observations?
2. What questions would you ask the Trial In-Charge?

Scenario A. The monitoring is taking place while a maize CFT is in flower. The team notices that a field of non-regulated maize has been planted 15 meters away from one border of the CFT, and the maize in that field is also in flower, and female flower silks are present. The Trial In-Charge is using tassel bags on the male flowers in the CFT as the only method of reproductive isolation, and the bags have been fastened to the plants using staples. The day before the monitoring team's visit, there was a storm in the area, with much wind, and the monitoring team notices a few tassel bags, with staples, laying in the rows between the GM maize plants.

Scenario B. The situation is identical to Scenario A, but the nearest maize field is 300 meters away.

Scenario C. The monitoring team is visiting a confined field trial of glyphosatetolerant cotton. The Trial In-Charge is using pollen trap rows as the only means of reproductive isolation. Five days ago, as a part of the agronomic evaluation, a field worker sprayed the plants with the herbicide glyphosate, just when the plants had formed flower buds. Some of the spray drifted onto the non-GM plants in the pollen trap rows, and many of the flower buds were damaged. The monitoring team notes that the GM cotton has begun to flower, but in the pollen trap rows, many of the damaged flower buds have not opened.

Scenario D. The situation is the same as in Scenario C, but the monitoring team's visit occurs later, after the GM cotton has finished flowering.

Scenario E. The monitoring team is visiting a confined field trial of potato plants. The Trial In-Charge is using temporal isolation as the only reproductive isolation method. The GM potato is an early flowering variety, flowering at 60 days postplanting, which is when the monitors' visit occurs. A neighbor is also growing potatoes in a field 50 meters away, using a late-flowering variety, flowering at 75 days post-planting. This growing season has been particularly warm, and the monitors note that the neighbor's potatoes are beginning to flower. In addition, the monitors note that bees have been visiting the flowers in the CFT.

How is Scenario E different from the other scenarios?

2.11 Completing the Monitoring Report

The Closing Meeting

At the completion of the visit, the monitoring team should meet with the PP/TIC/FIC.

- Present the finding and conclusions
- Agree on any corrective actions
- Discuss differences of opinion

Contents of the Report

- Completed forms, checklists, and team's notes
- Copies of applicable documents maintained by the PP/TIC/FIC
- Photographs
- Sketches, hand-drawn maps made during the visit
- References to the official site map

Reporting Risk Management Failure

Discussions of any risk management problems should be detailed and complete.

- What happened and how it apparently happened?
- Where and when?
- Who was present at the time?
- What corrective actions have been taken already and whether they have been successful?
- What other actions are recommended?

Reporting Risk Management Failure

The report should reflect the severity of the failure.

- Volunteers outside of the trial site
- Evidence of GE plants persisting in the environment
- Regulated GE plants being used as food/feed
- Large spills/releases of regulated GE plants
- Storage conditions that enable commingling

Administrative problems require less discussion.

Cases Needing Immediate Attention

- Team leader notifies Regulatory Authority by phone immediately, then in writing within 24 hours
- Regulatory Authority will advise team regarding any remedial action
- Team communicates to PP/TIC/FIC verbally immediately, then in writing within 24 hours
- PP/TIC/FIC will complete a Record of Corrective Action
- Monitoring team may schedule a follow-up visit

Completing the Report

- The team should promptly finalize the report.
- Copies of the report are sent to
- Regulatory Authority
- Monitoring body
- Permitted Party

2.12 Non-Compliance and Corrective Action

Non-Compliance

CFTs are very complicated experiments, and additional regulatory requirements make things more complicated.

- Some small instances of non-compliance are to be expected
- Missing entry in a record book
- Incomplete information on the CFT sign
- The monitoring team's job is twofold:
- Identify possible failures of regulatory compliance
- Detect minor problems that could lead to major risk management failures

Appropriate Corrective Measures

The goal of remediation is to restore containment of a storage facility or confinement of a CFT.

- It is impossible to anticipate every circumstance.
- The monitoring team needs to understand how risk management is accomplished so that they can recommend corrective measures with a reasonable likelihood of success.
- Corrective action should be a teaching opportunity for the PP/TIC/FIC.

Appropriate Corrective Measures

Every situation is different

- Administrative vs. Operational
- Incorrect information on label vs. seed spill at CFT site
- Immediate correction vs. temporary remediation + follow-up action
- Attach new label vs. mark area, recover seed + monitoring
- Consult with Regulatory Authorities
- Unpermitted CFT

The Cost of Corrective Measures

Undertaking a CFT requires the full commitment of the Permitted Party to comply with all confinement measures.

Failing to do so could result in unexpected, unbudgeted costs and the loss of data from the trial.

Examples: Corrective Measures

Inspection of Storage Facility

Observation	Corrective Measure	Comments
Storage container of GE plant material is not properly labelled.	Verify the identity of the material and place proper labels on the container.	If the identity of the material cannot be verified, it may need to be destroyed.

Record action in RoCA.

Examples: Corrective Measures

Inspection of CFT, In-Season

Observation	Corrective Measure	Comments
Isolation distance is too short; GE crop has not yet flowered.	• Remove rows; update map if necessary. • If there is not enough space to increase distance, bag flowers or remove flowers.	If no effective confinement measures are available, the trial may have to be destroyed.

Record action in RoCA.

Examples: Corrective Measures

Inspection of CFT, Post-Harvest

Observation	Corrective Measure	Comments
Prohibited plants found in post- harvest trial site. Plants have set seed.	• Destroy plants. • Extend post-harvest monitoring period to monitor for volunteers.	Follow-up visit may be necessary

Record action in RoCA.

Managing Corrective Measures

- Include in the monitoring report all corrective measures that were recommended.
- Provide a timeline in the monitoring report for the PP/TIC/FIC to comply with all corrective measures.
- Set a date with the PP/TIC/FIC when the monitoring team will return to verify that all corrective actions have been successfully implemented.

GROUP EXERCISE 9 – NON-COMPLIANCE AND CORRECTIVE ACTION

Using Scenarios A-E from Exercise 8, propose at least one mitigation measure for each situation that would help prevent a loss of confinement and bring the CFT back into compliance with the regulations. For each measure, explain why you think the measure is appropriate and estimate how effective it would be.

Scenario A

Scenario B

Scenario C

Scenario D

Scenario E

3. GROUP EXERCISES WITH ANSWER KEY AND NOTES

Group Exercise 1 – Assessment and Management of Risks Posed by Confined Field Trials

	Hazard	Exposure	Management Options	Management Effectiveness	Management Costs[1]
Polar bear attack	High	Very low, infrequent, variable	1. Stay away from bear habitat 2. Kill all bears 3. Bear repellent 4. Medical treatment		
Skin cancer from sun exposure	Medium to High	Variable	1. Sun screen 2. Stay indoors 3. Surgery, chemotherapy		
Loss of hearing from environmental noise	Low to Medium	Variable	1. Stay away from noisy areas 2. Use ear plugs 3. Redesign equipment to be quieter 4. Hearing aids		
Catching a cold	Low	Variable to High	1. Stay indoors 2. Good personal hygiene 3. Medications 4. Anti-microbial coatings		
Automobile accident	Low to High	Low to Variable	1. Don't drive or ride 2. Seat belts, air bags 3. Better traffic control 4. Better driver training 5. Higher insurance premiums		
Computer virus	Low to High	Low to High	1. Don't use the Internet 2. Don't share files 3. Anti-virus software		
Getting polio	High	Variable	1. Vaccinations 2. Avoid areas of prevalence 3. Medical treatment		

Go through the first example (polar bear attack) together with the participants, so they understand what they are supposed to do. There are no "right" or "wrong" answers, especially regarding effectiveness and costs of risk management, but there are a few goals for this exercise:

1. ***Get the participants to consider the hazard and exposure from several perspectives, not just their own.***
2. ***Encourage the participants to be creative in managing the risk. There may be 3 or more reasonable ways for each example.***
3. ***Encourage the participants to think of more than just financial costs. There may be cultural costs, psychological costs, ethical costs, environmental costs, etc.***

[1] Cost can include monetary costs, cultural costs, ethical costs, and so forth.

Group Exercise 2 – Risk Management Methods for Confined Field Trials

Crop	Characteristics	Confinement Challenges (when?)	Confinement Management (when?)
Maize	1. Wind pollinated 2. Insects collect pollen 3. Seeds attached to cob 4. Low seed dormancy 5. No vegetative propagation 6. Similar appearance to other grasses when seedlings	1. Pollen movement 2. Seed loss 3. Confusing seedlings of other species	1. Reproductive isolation 2. Volunteer monitoring
Cotton	1. Insect pollinated 2. No vegetative propagation 3. Sexually compatible relatives 4. Some seed dormancy	1. Keeping insect pollinators away during flowering	1. Reproductive isolation 2. Volunteer monitoring
Rice	1. Wind pollinated 2. Some seed shattering 3. Some seed dormancy 4. Sexually compatible relatives 5. Similar appearance to other grasses when seedlings	1. Pollen movement 2. Seed loss 3. Confusing seedlings of other species	1. Reproductive isolation 2. Volunteer monitoring
Bean	1. Self-pollinated 2. Som e insect pollination 3. Little dormancy 4. Some seedpod shattering 5. Sexually compatible relatives	1. Keeping insect pollinators away during flowering	1. Reproductive isolation 2. Volunteer monitoring
Banana	1. Vegetative propagation 2. Perennial	1. Asexual reproduction post-harvest	1. Volunteer monitoring

Go through the first example to make sure everyone understands what they are supposed to do. Not every group may be knowledgeable about every crop, so be prepared to help some of the groups. The goal is for the participants to understand that different crops have different confinement management challenges, and that some of the challenges occur at different times over the course of the CFT.

Group Exercise 3 – Transportation and Storage of Regulated GE Plant Materials

For the following three scenarios, list the containment issues that are raised and propose appropriate storage or transport measures that comply with the guidelines, including monitoring and reporting requirements.

Scenario A: A researcher is conducting experiments to develop GE sweet potato varieties. Her lab creates transgenic plants throughout the year, but she only has access to a greenhouse for six months each year, so she needs to store the GM potatoes until she is allowed to use the greenhouse. Her laboratory has a walk-in refrigerator that would provide year-round storage conditions for these potatoes as well as non-GM research materials.

- Confusing GE with non-GE, Sections B.2, B.3
- Vermin problems

Scenario B: A researcher will use cultured cells of cassava in his work to develop transgenic cassava plants. He intends to store transgenic cell lines in liquid nitrogen, using a liquid nitrogen storage tank that is maintained by his department and shared by all researchers.

- Confusing GE with non-GE, Sections B.2, B.3
- Securing the tank from unauthorized people, Section B.2

Scenario C: A university researcher has developed several GM banana varieties. He is using a greenhouse to grow small banana plantlets in pots. A colleague at another university has requested ten of these plants to grow in an enclosed growth chamber at her university. The plantlets are 25 cm tall, and they must be shipped with soil around the roots.

- Size and durability of containers, ability to keep plants viable, Section A.2, A.3

Identifying the issues should be fairly easy for the groups. The challenge is to find ways to deal with the challenges. Try to encourage multiple solutions, and make sure they are realistic in the laboratory setting.

Group Exercise 4 – Planting and Maintaining the Confined Field Trial

Exercise A. You are in the process of inspecting a confined field trial for GM cotton. The Trial In-Charge has provided you with the attached map of the field trial site. Review the map and indicate on the map any information that is missing. In the space below, explain why this missing information is important to the proper management of risks from the trial.

- 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.
- Maps must provide details on the layout of the site and distances between the field trial site and surrounding features.
- The dimensions of the trial site and distances to physical landmarks must be accurately reported.
- Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.
- Total area planted with the regulated material, including negative controls and any border or guard rows when used (acres or square meters).
- Identification of any natural ecosystems adjacent to the trial site (natural habitats, waterways, garden, orchard, forests, and woodlots, hedgerows), wherever reasonable.
- Planting date.
- Compass directions, with North at the top of the page.

Exercise B. Each crop may pose different challenges to the Trial In-Charge when trying to meet the various requirements for managing a confined field trial. In the table below, think about the biology of the crops provided, and list the challenges that may be encountered meeting the specific requirements when conducting a field trial with that crop. Then suggest measures that may help the Trial In-Charge ensure effective reproductive isolation of the crop.

C.2.1.	Requirement	Compliance Challenges and Suggestions
Tobacco	C.2.1.	tiny seeds, hard to remove from planting equipment and tools and difficult to collect effectively for destruction
Mustard	C.3.2.	small seedlings, seeds germinate quickly
Radish	C.3.6.	plants grow quickly, buds are small and inconspicuous, and plants flower early
Rice	C.6.1.	seeds may be difficult to remove from soil, some seed dormancy, seedlings look like other grasses

Non-regulated Cotton
Road #12
House
Road #45
Maize Field
Regulated Cotton Trial
Non-regulated Cotton
Trial Manager: Mr. Tom Jones
Telephone: (555) 123-4567
Total area planted to field trials: 4400 m²
Crop species: Gossypium hirsutum (cotton)
Location: Con-12, Lot 45, Heathcote County, Landmark Township, NC
Permit No.: 04-0250-99n
Date: May 14, 2004

Group Exercise 5 – Reproductive Isolation Methods

Although there are several effective reproductive isolation methods, not all of them work well with all crops. In the table below, you have been given several combinations of crops and reproductive isolation methods. Indicate in the right column the challenges facing the Trial In-Charge to effectively implement reproductive isolation. Then suggest measures that may help the Trial In-Charge ensure effective reproductive isolation of the crop.

Crop	Reproductive Isolation Method	Implementation Challenges and Suggestions
Maize	Flower structure removal	Workers may miss some flowers
Cotton	Pollen trap rows	Trap rows must flower at the same time as the GE crop Trap row planting density must be comparable to GE crop Trap row stand/health must be adequate
Mustard	Temporal isolation	Timing of flowering may be affected by weather conditions
Rice	Flower bagging	Bags can fall off Workers may miss some of the flowers Bags may allow pollinators to enter
Sorghum	Spatial isolation	Inspecting isolation zone for volunteers or non-GE sorghum plantings

The goal for this exercise is for the participants to realize that reproductive isolation is neither automatic nor easy. Each method has challenges to implement successfully, and monitoring is key to ensuring confinement.

Group Exercise 6 – Harvest and Disposition of Regulated GE Plant Material

Each crop may pose different challenges to the Trial In-Charge when trying to meet the various requirements for harvesting a confined field trial. In the table below, think about the biology of the crops provided, and list the challenges that may be encountered meeting the specific requirements when conducting a field trial with that crop. Then suggest measures that may help the Trial In-Charge ensure effective confinement of the crop.

Crop	Requirement	Challenges
Tobacco	D.2.2.	Very small seeds would be easy to drop and difficult to recover
Sweet Potato	D.3.1.	Tubers and cut stems could re-sprout
Banana	E.3.5.	Side shoots could sprout from main stem
Rice	E.4.1.	Rice seeds exhibit some dormancy, resulting in residual germination over time.

The goal is to gain familiarity with the guideline provisions. By this time, the participants should be having less trouble answering the questions.

Group Exercise 7 – Introduction to Monitoring of Confined Field Trials

Over the course of a confined field trial, there are several key stages when crucial activities are taking place, and a monitoring team may be called in specifically to observe these activities.

- Pre-planting
- Planting
- Anthesis
- Harvest
- Post-harvest, including termination and post-termination activities

Monitoring is always a valuable practice, at any stage of the CFT, but certain factors, such as the crop that is being tested, suggest specific times when monitoring will be especially useful. For the following crops, consider their reproductive biology and other characteristics and suggest which of the above stages in the course of a CFT should be the focus of monitoring activity, if only one or two monitoring visits was possible. Please explain your choices.

1. Maize

Anthesis

Post-harvest

2. Common bean

Post-harvest

3. Cotton

Anthesis

Post-harvest

4. Banana

Post-harvest

The challenge here will be that most of the groups may feel that more than two monitoring visits are necessary. That is OK, let them explain their choices, and then ask, which of the visits are most crucial for ensuring proper confinement.

Group Exercise 8 – Monitoring Process

Below you will find three scenarios, describing observations made by a monitoring team during a visit to a CFT. For each scenario, answer two questions:

1. What is your reaction, as a monitor, to the observations?
2. What questions would you ask the Trial In-Charge?

Scenario A. The monitoring is taking place while a maize CFT is in flower. The team notices that a field of non-regulated maize has been planted 15 meters away from one border of the CFT, and the maize in that field is also in flower, and female flower silks are present. The Trial In-Charge is using tassel bags on the male flowers in the CFT as the only method of reproductive isolation, and the bags have been fastened to the plants using staples. The day before the monitoring team's visit, there was a storm in the area, with much wind, and the monitoring team notices a few tassel bags, with staples, laying in the rows between the GM maize plants.

Possible failure of reproductive isolation

When were the tassel bags put on?

Can the TIC identify bags that were actually used, versus ones that were merely discarded in the field by the workers?

Scenario B. The situation is identical to Scenario A, but the nearest maize field is 300 meters away.

300 meters may be far enough away to serve as backup spatial isolation.

Scenario C. The monitoring team is visiting a confined field trial of glyphosatetolerant cotton. The Trial In-Charge is using pollen trap rows as the only means of reproductive isolation. Five days ago, as a part of the agronomic evaluation, a field worker sprayed the plants with the herbicide glyphosate, just when the plants had formed flower buds. Some of the spray drifted onto the non-GE plants in the pollen trap rows, and many of the flower buds were damaged. The monitoring team notes that the GE cotton has begun to flower, but in the pollen trap rows, many of the damaged flower buds have not opened.

Possible failure of reproductive isolation, due to inadequate trap row stand.

Where is the nearest cotton field?

Are the GE plants producing pollen?

Scenario D. The situation is the same as in Scenario C, but the monitoring team's visit occurs later, after the GM cotton has finished flowering.

Failure of reproductive isolation is likely?

Where is the nearest cotton field?

Scenario E. The monitoring team is visiting a confined field trial of potato plants. The Trial In-Charge is using temporal isolation as the only reproductive isolation method. The GM potato is an early flowering variety, flowering at 60 days postplanting, which is when the monitors visit occurs. A neighbor is also growing potatoes in a field 50 meters away, using a late-flowering variety, flowering at 75 days post-planting. This growing season has been particularly warm, and the monitors note that the neighbor's potatoes are beginning to flower. In addition, the monitors note that bees have been visiting the flowers in the CFT.

Possible failure of reproductive isolation

Are the flowers in the neighboring field receptive to pollen?

How is Scenario E different from the other scenarios?

Potato fruits are not eaten, and the tubers will not be transgenic, so theoretically it is possible that the above ground portions of the plant could be destroyed, while allowing the farmer to keep the tubers. (This is not for the monitors to decide, however, it is a GEAC question.)

This is the most important exercise in the workshop. Make sure the participants understand the case studies completely, and ask them follow up questions to verify they understand. Don't provide answers too soon—if one group is struggling, let another group help them out.

Group Exercise 9 – Non-Compliance and Corrective Action

Using Scenarios A-E from Exercise 8, propose at least one mitigation measure for each situation that would help prevent a loss of confinement and bring the CFT back into compliance with the regulations. For each measure, explain why you think the measure is appropriate and estimate how effective it would be.

Scenario A

Detasseling

Trial destruction

Destruction of neighboring maize field

Scenario B

Detasseling

Scenario C

Netting to preclude pollinators

Trial destruction

Scenario D

Trial destruction

Trap row destruction

Destruction of any nearby cotton fields

Scenario E

Netting to preclude pollinators

Flower removal/bagging

Destruction of fruit (fruit is not eaten, so no risk of food commingling)

This is another important exercise. Let the groups be creative in suggesting corrective measures, but always ask how the suggestion will help restore confinement or prevent further gene flow.

4. CFT Monitoring Workshop Quiz

Welcome to the CFT Monitoring Workshop Quiz

*** 1. Please provide your contact information.**

Name

Organization

Email

*** 2. Research conducted in a greenhouse is an example of**

- ☐ Confined research
- ☐ General release
- ☐ Contained research
- ☐ None of the above

*** 3. What is the primary regulatory challenge in permitting the first CFT of a new GE plant variety?**

- ☐ The cost is very high.
- ☐ The researcher will not understand how to complete the application.
- ☐ Less is known about the environmental risks posed by the plant.
- ☐ The public will object to the CFT.

*** 4. CFTs may result in the collection of the following types of data about the GE plant.**

SELECT ALL CORRECT ANSWERS

- ☐ Weediness potential
- ☐ Environmental fate of novel plant-expressed proteins
- ☐ Consumer taste preference
- ☐ Crop nutritional content
- ☐ Interactions with other organisms in the environment
- ☐ Market value of the crop

*** 5. A map of the proposed CFT is not required to be included with the CFT application.**

- ☐ True
- ☐ False

*** 6. A developer of a GE cotton plant has applied for authorization of Biosafety Research Level I CFT. In her application the developer proposed to establish 15 trials in different locations, using a total of 18 acres. Her application was denied for the following reason.**

- ☐ An applicant can have no more than 10 trials under a single application.
- ☐ Some of the proposed trials are larger than 1 acre.
- ☐ Both of the above
- ☐ None of the above

*** 7. Regulators need to see the contingency plan for accidental releases when they evaluate the CFT application.**

- ☐ True
- ☐ False

*** 8. General, unconfined release of a GE plant into the environment relies on what factor to ensure safety?**

- ☐ Reproductive isolation
- ☐ Rigorous risk assessment
- ☐ A physical structure

*** 9. Which of these are effective risk management measures for CFTs?**

SELECT ALL CORRECT ANSWERS

- ☐ Keep the location of the CFT a secret.
- ☐ Limit the size of the CFT.
- ☐ Limit the number of workers at the CFT site.
- ☐ Maintain reproductive isolation of the GE crop.

*** 10. Which one of the following statements is true?**

- ☐ CFT confinement measures help reduce allergenicity.
- ☐ CFT confinement measures reduce the environment's exposure to the GE plant.
- ☐ CFT confinement measures are generally used when a GE plant is grown commercially.
- ☐ CFT confinement measures are unrelated to risk reduction.

*** 11. How can risks resulting from the growth of GE plants be reduced?**

SELECT ALL CORRECT ANSWERS

- ☐ Reduce the hazard posed by the GE plant.
- ☐ Reduce the exposure of the GE plant to the environment.
- ☐ Reduce both hazard and exposure.
- ☐ Risks from growing GE plants cannot be reduced.

*** 12. Because risks from CFTs are managed differently than risks from commercial releases of GM plants, applications for CFTs typically contain . COMPLETE THE SENTENCE:**

- ☐ More information than applications for commercial releases.
- ☐ Less information than applications for commercial releases.
- ☐ The same amount of information as applications for commercial releases

*** 13. What information is needed about the pollen of the plant in an application for a confined field trial that will help design appropriate risk management measures?**

SELECT ALL CORRECT ANSWERS

- ☐ Color
- ☐ Longevity/viability
- ☐ Whether it is carried by wind or insect vectors
- ☐ Whether it causes allergic reactions
- ☐ All of the above

*** 14. It is possible that the same methods soybean breeders use to mitigate pollen-mediated gene flow may be effective for a GE soybean variety, grown in a CFT.**

- ☐ True
- ☐ False

*** 15. It is known that canola can hybridize with sexually compatible relatives. What other key piece of information is needed to assess the hybridization potential from a CFT of GE canola?**

- ☐ Whether seed will be produced by the canola plants in the CFT
- ☐ Whether the planter has been thoroughly cleaned after the CFT was planted.
- ☐ Whether any sexually compatible relatives of canola are present in the region where the CFT will take place.

*** 16. The most important information to have in the selection of appropriate confinement measures for a GM plant is:**

- ☐ The economic value of the plant
- ☐ The popularity of the plant with farmers.
- ☐ The number of uses for the plant.
- ☐ The biology of the plant.

*** 17. Data regarding which of the following topics are most relevant to the risk management of a CFT?**

- ☐ Toxicity/Allergenicity
- ☐ Reproductive biology
- ☐ Weediness

*** 18. Why might post-harvest restrictions on a maize CFT extend for one year for maize, but for canola, the restrictions may extend for several years?**

- ☐ Canola seeds are much smaller than maize seeds.
- ☐ Canola seeds remain viable in the soil for many years longer than maize seeds.
- ☐ Maize is wind pollinated.
- ☐ None of the above

*** 19. Although soybean is self-pollinated and maize is wind pollinated, it is likely that the same reproductive isolation techniques will be effective with both species.**

- ☐ True
- ☐ False

*** 20. Generally, shipping containers for GE plant material consist of primary, secondary, and tertiary containers.**

- ☐ True
- ☐ False

*** 21. Primary containers for GM plant material may be reused if properly cleaned.**

- ☐ True
- ☐ False

*** 22. What 3 actions should follow the discovery of an accidental release during the transportation of GM plant material?**

- ☐ Notify the appropriate regulatory authorities
- ☐ Terminate the CFT.
- ☐ Destroy the packaging.
- ☐ Mark the area where the release occurred.
- ☐ Call the police.
- ☐ Try to collect as much of the material as possible.

*** 23. Storage container labels are there to warn people that GE plant material is dangerous.**

- ☐ True
- ☐ False

*** 24. Why is pest control necessary in storage facilities for GE plant material?**

- ☐ Because this material is extremely valuable.
- ☐ Because pests that consume GE plant material could be harmed.
- ☐ Because pests can damage storage containers, increasing the risk of an accidental release of GE plant material.

*** 25. Which of the following statements is true?**

- ☐ Conventional seed and regulated, GE seed can be shipped together, when properly labelled, in the same primary container.
- ☐ Conventional seed and regulated, GE seed can be shipped together, when properly labelled, in the same secondary container.
- ☐ Conventional seed and regulated, GE seed cannot be shipped together, under any circumstances.

*** 26. Which aspect of risk management of a CFT is the most critical?**

- ☐ Preventing impacts to the land where the CFT is performed.
- ☐ Keeping the GE plant out of the food/feed supply.
- ☐ Protecting CFT workers from harm.
- ☐ Keeping a GE trait from introgressing into a weed species.

*** 27. When selecting a site for a CFT of a GE plant, the researcher must consider how reproductive isolation will be accomplished at the site.**

- ☐ True
- ☐ False

*** 28. Which of the following are good ways to identify the boundaries of a field trial site?**

SELECT ALL CORRECT ANSWERS:

- ☐ A satellite photograph
- ☐ A map with distances to permanent landscape features
- ☐ GPS coordinates
- ☐ A street address
- ☐ Semi-permanent, visible marker flags

*** 29. The researcher should regularly review the site map throughout the trial to make sure that the map continues to accurately reflect the site.**

- ☐ True
- ☐ False

*** 30. If a seed planter was previously used to plant a non-GE crop, it is not required to be cleaned before being used to plant a CFT.**

- ☐ True
- ☐ False

*** 31. What 3 actions should follow the discovery of an accidental release of regulated plant material from the trial site?**

SELECT ALL CORRECT ANSWERS

- ☐ Mark the area where the incident occurred.
- ☐ Terminate the CFT.
- ☐ Notify the appropriate regulatory authorities.
- ☐ Collect as much of the material as possible.
- ☐ Call the police.

*** 32. Different isolation distances are needed for different crops.**

- ☐ True
- ☐ False

*** 33. Any reproduction isolation method chosen for a CFT must be used to completely surround the site.**

- ☐ True
- ☐ False

*** 34. A researcher wishes to plant a CFT with GE cassava (*Manihot esculenta*) in an area where Manihot glaziovii, a wild sexually compatible species, is known to exist. She intends to establish spatial isolation of 100 m for the CFT. Regulators should not allow any cassava or M. glaziovii plants to grow within 100 m of the CFT.**

- ☐ True
- ☐ False

*** 35. For a pollen trap crop to provide effective reproductive isolation, the following must be true.**

SELECT ALL CORRECT ANSWERS:

- ☐ Anthesis for the GE plants and the pollen trap plants must happen at the same time.
- ☐ The trap plants must be sprayed to control insects.
- ☐ The trap plant rows must form an uninterrupted border around the CFT.
- ☐ The trap plant rows must be monitored to make sure there is a good stand of plants.

*** 36. Pollen traps can provide effective reproductive isolation with**

- ☐ Insect pollinated crops
- ☐ Wind pollinated crops
- ☐ Self-pollinated crops
- ☐ All of the above
- ☐ None of the above

*** 37. A researcher is planning to use only early crop destruction as reproductive isolation. What factor is the best argument for adding spatial isolation as well?**

- ☐ There is plenty of open land around the CFT site.
- ☐ The GM crop is wind pollinated.
- ☐ The growing conditions in the area vary from year to year.
- ☐ There are plenty of field workers to manage the land.

*** 38. Which of the following goals are important for ensuring confinement when harvesting a CFT?**

SELECT ALL CORRECT ANSWERS

- ☐ Keep any GE plant material out of the food/feed chain.
- ☐ Collect good scientific data from the CFT.
- ☐ Prevent persistence of the GE plant in the environment.

*** 39. If the researcher has permission from the regulatory authorities, she may keep seeds and other GE plant material produced during a CFT.**

- ☐ True
- ☐ False

*** 40. A researcher has used non-GE cotton plants as a pollen trap for his GE cotton CFT. After the GE cotton is harvested in compliance with all regulations, the researcher may harvest the non-GE cotton plants and sell the cotton produced by them.**

- ☐ True
- ☐ False

*** 41. After the harvest of a CFT of GE maize, the researcher wants take maize leaves and stalks back to the lab to analyze them for nutritional content. This is OK, but only if:**

SELECT ALL CORRECT ANSWERS:

- ☐ The GE trait is expected to affect nutritional content.
- ☐ He has permission from the regulatory authorities.
- ☐ Regulatory authorities have approved his transport and storage protocols.
- ☐ It is not OK. He cannot remove this material from the site.

*** 42. Planting non-GE maize on a site immediately after a GE maize CFT has been harvested is not allowed because this practice can make it difficult to ? FILL IN THE BLANK.**

- ☐ Evaluate environmental impacts
- ☐ Locate GE maize volunteers
- ☐ Collect crop performance data
- ☐ Harvest the non-GE crop

*** 43. A researcher must monitor the field after his CFT was terminated. When is the most critical time for monitoring?**

- ☐ Whenever there are insect pollinators present.
- ☐ Whenever weather conditions favor seed germination.
- ☐ Whenever neighboring fields are harvested

*** 44. The CFT manager is monitoring the trial site for a maize CFT several months after harvest. During the prior week it had rained, and during his visit to the site, the manager notices a few small maize seedlings growing in the trial site.**

- ☐ This is an example of an accidental release, and the manager must notify the regulatory authorities.
- ☐ This is an example of an accidental release, but the manager can simply destroy the seedlings.
- ☐ This is not an example of an accidental release, but the manager should destroy the seedlings.

45. The primary function of CFT monitoring is to

- ☐ Provide advice to the applicant regarding how to assess environmental risks from GE plants
- ☐ Verify that the applicant is correctly carrying out all the necessary risk management practices for the CFT
- ☐ Oversee the collection of data from the CFT
- ☐ Determine whether the applicant has violated any regulations.

*** 46. The frequency of monitoring needed for a particular CFT can be influenced by**

SELECT ALL CORRECT ANSWERS

- ☐ The cost of the CFT
- ☐ The crop species
- ☐ The GE trait
- ☐ The size of the CFT

*** 47. Which pieces of evidence should monitors consider when evaluating risk management of a CFT?**

SELECT ALL CORRECT ANSWERS

- ☐ Interviews with personnel
- ☐ Standard Operating Procedures developed by the applicant
- ☐ Scientific articles published by the researcher conducting the CFT
- ☐ Direct observation of the CFT
- ☐ Management records maintained by the trial manager
- ☐ Past monitoring reports regarding the CFT.

*** 48. When the monitoring team sees a potential failure of risk management, they should include the following information in the report:**

- ☐ A. The date of the incident
- ☐ B. A description of what happened
- ☐ C. A determination of which regulations were violated
- ☐ D. A description of any mitigation measures that were implemented
- ☐ A, B, and C
- ☐ A, B, and D
- ☐ A, B, C, and D

*** 49. Monitors should determine whether a particular lapse of risk management is serious or not and whether or not remedial action must take place immediately.**

- ☐ True
- ☐ False

*** 50. Monitors must treat information collected during a site visit to a CFT as confidential.**

- ☐ True
- ☐ False

*** 51. If the monitoring term determines that a problem exists at the CFT site that requires urgent attention, the must notify the Regulatory Authority:**

- ☐ Immediately by telephone and in writing by 72 hours
- ☐ By telephone within 24 hours and in writing by 72 hours
- ☐ Immediately by telephone and by email within 48 hours
- ☐ Immediately by telephone and in writing by 24 hours

52. An example of a situation for which the monitoring team should require immediate attention is:

- ☐ The Notice Board has not been posted at the trial site.
- ☐ Imminent release of regulated plant material is likely.
- ☐ The Trial In-Charge does not have a copy of the Record of Planting.

*** 53. The monitoring team notes that the designated storage cabinet for regulated plant material is lockable, and the staff routinely leave the key in the lock, to keep the key from getting misplaced. Is this in compliance with the Standard Operating Procedures for Storage?**

- ☐ Yes
- ☐ No

*** 54. During a post-harvest inspection, which of these situations should the monitoring team treat as the most urgent?**

- ☐ There are prohibited plants growing on the CFT site.
- ☐ Signs for the CFT are not being maintained.
- ☐ Wild animals have been entering the CFT site.

*** 55. While the monitoring team is inspecting the harvest of a maize CFT, the Trial In-Charge asks if some of the maize leaves can be brought back to the lab for nutritional analyses. The Trial In-Charge has containers originally used to bring the seed for planting to the site, and the containers were approved for transporting seed. The Trial In-Charge proposes to use these containers for the leaves.**

The monitoring team does not allow the leaves to be transported from the CFT site. What reason or reasons should the team give to the Trial In-Charge?

- ☐ A. The containers were not approved for transporting leaves.
- ☐ B. Leaves must always be destroyed at the trial site.

- ☐ C. The Trial In-Charge did not have prior authorization from the Regulatory Authority to retain regulated plant material after the termination of the CFT.
- ☐ A and B
- ☐ A and C
- ☐ A, B, and C

*** 56. Once the CFT has been harvested, there is no need to mark the corners of the trial site.**

- ☐ True
- ☐ False

*** 57. Monitors must be ready to suggest appropriate corrective measures to remediate risk management failures discovered during the inspection.**

- ☐ True
- ☐ False

*** 58. It is possible that the monitoring team may determine that no remedial action will correct a serious risk management lapse. In this case, the CFT may need to be terminated.**

- ☐ True
- ☐ False

*** 59. It is always preferable for the monitoring team to identify problems early, when they can be more easily remediated. Serious failures of confinement can lead to**

- ☐ Pre-mature termination of the CFT
- ☐ Loss of research data
- ☐ Wasted research funding
- ☐ Enhance scrutiny for subsequent CFT applications from the same applicant
- ☐ All of the above

*** 60. For very serious lapses of risk management that undermine the confinement of the CFT, the monitoring team may recommend interim remedial measures, pending a full consultation with the DBT.**

- ☐ True
- ☐ False

*** 61. The monitoring team should give the Permitted Party deadlines when specific remedial measure must be completed and whether the team will need to return for an additional inspection to verify that all measures were completed.**

- ☐ True
- ☐ False

*** 62. Which of the following activities should the monitoring team not do in the final monitoring report?**

SELECT ALL CORRECT ANSWERS

- ☐ Recommend appropriate remedial measures to the Trial In-Charge
- ☐ Provide legal advice regarding regulatory infractions
- ☐ Critique the experimental goals of the CFT
- ☐ Advise the Permitted Party as to the potential severity of individual risk management lapse that were found during the inspection.

5. Post Workshop Questionnaire

Thank you for attending the Workshop on Monitoring of Confined Field Trials of Regulated GE Plants.

In order to evaluate the workshop, please provide responses to the questions below by ____. Your feedback is important to us and will be used to improve future events.

1. Please rate the following for this event:

	Too short	Just right	Too long
The length of the workshop	○	○	○

Please provide any additional comments about this aspect of the event.

2. Please rate the following for this event:

	Poor	Fair	Good	Very Good	Excellent
The usefulness of the workshop exercises	○	○	○	○	○

Please provide any additional comments about this aspect of the event.

3. Please rate the following presentation in terms of overall quality and usefulness:

	Poor	Fair	Good	Very Good	Excellent
Regulation of CFTs.	○	○	○	○	○
Assessment and Management of Risks Posed by CFTs	○	○	○	○	○
Risk Management Methods for CFTs	○	○	○	○	○
Transportation and Storage of Regulated GE Plant Materials	○	○	○	○	○

Planting and Maintaining the CFT	○	○	○	○	○
Reproductive Isolation Methods	○	○	○	○	○
Harvest and Disposition of Regulated GE Plant Material	○	○	○	○	○
Introduction to the Monitoring of CFTs	○	○	○	○	○
Monitoring Process	○	○	○	○	○
Non-Compliance and Corrective Action	○	○	○	○	○
Preparing the Monitoring Report	○	○	○	○	○

Please provide any additional comments about these presentations.

		The sameas before	Slightly better than before	Much better than before
4.	**Please provide information on the following:** How would you rate your knowledge of Risk Assessment AFTER the workshop, compared to BEFORE the workshop?	○	○	○
5.	**Please provide information on the following:** How would you rate your knowledge of the Management of Risks Posted by CFTs AFTER the workshop, compared to BEFORE the workshop?	○	○	○
6.	**Please provide information on the following:** The same as before Slightly better than before Much better than before How would you rate your knowledge of the Transportation and Storage of Regulated GE Plant Materials AFTER the workshop, compared to BEFORE the workshop?	○	○	○
7.	**Please provide information on the following:** How would you rate your knowledge of the Planting and Maintenance of CFTs AFTER the workshop, compared to BEFORE the workshop?	○	○	○
8.	**Please provide information on the following:** How would you rate your knowledge of the Harvest and Disposition of Regulated GE Plant Material AFTER the workshop, compared to BEFORE the workshop?	○	○	○
9.	**Please provide information on the following:** How would you rate your knowledge of the Monitoring Process AFTER the workshop, compared to BEFORE the workshop?	○	○	○
10.	**Please provide information on the following:** How would you rate your knowledge of Non-Compliance and Corrective Action AFTER the workshop, compared to BEFORE the workshop?	○	○	○

11. What aspect of the workshop was the most valuable to you and why?

12. How do you think you will use the knowledge you gained from the workshop?

13. Would you recommend this workshop to others?

- ○ Yes
- ○ No

14. Please feel free to provide any additional feedback that you would like to share with us.

15. Please provide your contact information.

Name

Organization

Email Address

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