UNITED REPUBLIC OF TANZANIA

BIOSAFETY INSPECTOR'S MANUAL FOR CONFINED FIELD TRIAL REQUIREMENTS IN TANZANIA

A Procedural Guide for Biosafety Inspectors Conducting Inspections of Confined Field Trials of Regulated Genetically Engineered (GE) Plants and Plant Products in Tanzania

VICE PRESIDENT'S OFFICE **DECEMBER 2012**

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PREFACE

Modern biotechnology is opening new frontiers in many fields particularly agriculture, health and industry. However, its development and application has been associated with environmental, health, ethical and socio-economic concerns. Therefore, in order to tap the benefits arising from modern biotechnology, it is of priority to institute biosafety measures that would ensure its safe transfer, handling and use. In relation to this, Tanzania has already put in place Environmental Management Act of 2004; Biosafety Regulations of 2009; and National Biosafety Framework, which address this challenge.

Confined field trial represents a small-scale experimental field trial prior to environmental release of genetically modified plants that is performed in a manner and conditions that mitigate impacts on the surrounding environment. At the point of confined field trial, the potential environmental risks of a particular transgenic plant may not be fully understood and this poses challenge to regulatory oversight and environmental risk management. In this regard, a confined field trial requires effective control through Regulatory Authorities and therefore the need for guidance during biosafety inspections which has necessitated the preparation of this Manual.

This Manual is intended as a guide to Biosafety Inspectors for carrying out efficient and effective inspections of confined field trials. The Manual outlines procedures and steps to be followed before, during and after inspection.

It anticipated the Manual would be revised periodically to accommodate emerging issues as need arises. Therefore, suggestion for improvement would be highly appreciated.

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ABBREVIATIONS AND ACRONYMS

CFT	Confined Field Trial
CFTD	Confined Field Trial Directive
DNA	Deoxyribonucleic acid
GE	Genetically engineered
GEF	Global Environment Facility
GM	Genetically modified
GMOs	Genetically modified Organisms
GPS	Global positioning System
NBF	National Biosafety Framework For Tanzania
NBFP	National Biosafety Focal Point
NEMC	National Environment Management Council
UNEP	United Nations Environment Programme
TPRI	Tropical Pesticides Research Institute

DEFINITION OF TERMS

Accidental release	Any unauthorized release of a Regulated GE plants in the environment, the human food and/or livestock feed chains.
Anthesis	The time when flowering or pollination of a flower is complete.
Authorized Party	The addressee on the notification of authorization as defined in the Confined Field Trial Directive 2004 (Schedule 18) of the Plant Protection Regulations 1999.
Breach	Break, violate or contravene with specified conditions.
Compliance	Fulfilling the requirements of all of the terms and conditions of authorization
Confinement	Restriction of an organism and its genetic traits to a specific and defined area of the environment, called 'trial site'
Confined Field Trial Directive	The Guidelines provided under the Plant Protection Regulations (1999) of the Plant Protection Act 1997.
Confined Field Trial Permit	The permit issued to the Authorized Party as permission to undertake confined field trial in Tanzania.
Early termination	Termination of a trial before anticipated completion date.
Facility Manger	A person who is responsible in the supervision of the storage facility.
Field trial	The planting of one or more Regulated Genetically Engineered plants in a single experiment.
Free-living	means that the plants grow outside of cultivation or where they have not been planted.
Genetic engineering	The genetic modification of organisms by recombinant DNA techniques.
Genetically Engineered (GE) **Plants and Plant products**	Plants and plant products developed through genetic modification of organisms by recombinant DNA techniques.
Material confinement:	Measures taken to ensure that GM plant material is not consumed by humans or livestock.
Primary container	The container into which Regulated GE plants and plant products is placed.
Prohibited Plant	Any plant found growing within the spatial isolation distance surrounding

	a confined field trial that is sexually compatible with the genetically engineered plant species grown within the confined field trial.
Receiver	A person who has been appointed by the Authorized Party to receive the Regulated GE plants and plant products for storing in the storage facility
Regulated Genetically Engineered (GE) **plants and plant products**	Plants and plant products not yet approved for use in the country and have been developed through genetic modification of organisms by recombinant DNA techniques.
Reproductive isolation	Means of separation of GE plants and any volunteer plants that may arise in the field trial site from sexually compatible plant species in the environment.
Sanitized	Determined to be free of all Regulated GE plants and plant products based on visual inspection.
Sealed containers	Containers that are leak proof and secured.
Secondary container	The container into which a primary container is placed
Sexually compatible	means that two plants can cross-pollinate with each other yielding viable hybrids without human intervention.
Shipper	An agent, company or a person that transports the Regulated GE plants and plant products between research facilities, storage facilities, quarantine station, and field trial sites in Tanzania.
Spatial isolation	A method of achieving reproductive isolation by separating organisms in the Trial sites by a defined distance from prohibited organisms. Regulatory Authority: The government body having a statutory authority to regulate an activity.
Tertiary container	The container into which a secondary container is placed.
Trial site location	The geographic location of a trial site as identified by an address, legal land location, or GPS coordinates.
Trial Site Manager	A person who is responsible in the supervision of the Confined Field Trial site.
Trial Site Manager	A person who is responsible in the supervision of the Confined Field Trial site.
Trial site	The area of a trial that is confined by one or more continuous methods of reproductive and/or material isolation.

1.0 INTRODUCTION

Tanzania recognizes the potential benefits of modern biotechnology in agriculture, human and animal health, industrial and agricultural production as well as in many other sectors. Through modern biotechnology it is possible to modify the genetic makeup of an individual plant, animal or any other cellular organism and non-cellular entities such as plant and animal viruses. The genetic modification of these organisms or entities alters their characteristics. The primary goal of genetic modification is usually to overcome a pre-defined problem, for example, generate resistance to plant pathogens or increase water use efficiency et cetera. It is therefore understandable that there have been efforts to create favorable environment for research on genetically modified organisms (GMOs). Despite the potential benefits attached to the use of GMOs, their handling differs so much from the way conventionally produced plants and other organisms are handled. In modern biotechnology, recombinant DNA technology is used to alter genetic constitution of individuals as opposed to natural processes. Thus there are concerns over research, use and release of GMOs in the environment. For example, it is feared that there could be gene flow from GM plants to their relative species in the environment. There are also ethical concerns on the use of GMOs. Consequently, use of and research on GMOs are regulated in Tanzania and other countries in the world.

In Tanzania, guidelines and practical manuals have been developed in order to enable safe use of GMOs. The documents in place include National Biosafety Framework For Tanzania (NBF), National Biosafety Guidelines, Manual for Emergence Response, manual for contained use of GMOs. Biosafety Inspectors Manual is meant to facilitate monitoring research activities and use of GMOs in the country. The manual for Biosafety Inspectors is required in order to achieve consistence, effectiveness and efficiency in monitoring and collecting biosafety information and making follow-ups on confined field trials of GE plants. It is a working tool intended for use by the Biosafety Inspectors responsible for the enforcement of Confined Field Trial Directive (CFTD-

Schedule 18) of the Plant Protection Regulations 1999 in Tanzania.

In order to achieve the goals of conducting the confined field trials safely, it is important to establish a good working relationship between the Regulators and the Applicants/Authorized Party. The pre-established good working relationship can also resolve problems much quicker.

Regulatory Inspectors are regularly trained and are provided with the Inspection manual for use routinely. To make best use of this manual, Inspectors should read it and become familiar with this document together with other documents mentioned above. Whereas this manual is intended for Inspectors, the information contained herein is also useful to other stakeholders such as Authorized Party, Trial (site) manager or other personnel who are involved in conducting GMOs activities.

The Biosafety Inspector's mission is to conduct a good field site inspection to determine if the Authorized Party is in compliance also to give education on self-compliance so as to reduce the need for frequent inspections. This manual gives a guide and presents a rationale for when and where to conduct an inspection. The inspection forms annexed to this manual should enable Biosafety Inspectors to compile detailed reports about confined field trial activities. This manual should be used together with other manuals and guidelines on safe use of GMOs. The inspectors should also be fully informed on terms and conditions of GMO activity approval.

2.0 OBJECTIVES

The main objective of this manual is to provide instructions and guidance to the Biosafety Inspectors conducting inspections of confined field trials of genetically modified plants in enforcing Biosafety Regulations and Guidelines for CFT. The Specific objectives include:

i. Enabling Biosafety inspectors prepare for inspections

ii. Guiding the biosafety inspectors when carrying out actual inspections
iii. Guiding inspectors on a stepwise inspection of GE plants activities
iv. Guiding inspector on handling and reporting non-compliance incidents
v. Guiding inspectors prepare useful biosafety reports
vi. Help trial managers and Authorized Party to prepare for CFT Inspections

To achieve the above objectives, this manual is organized in a way that enables Biosafety Inspector to prepare him/herself for inspection, conduct an actual inspection, and finally prepare and submit a written report on confined field trials. It narrates the requirements, procedures and critical aspects for each inspection step and guides the Biosafety Inspector on actions to be taken under given circumstances. Taken together, the manual covers aspects of storage, transport, current season field trials, harvest, trial termination and disposal of GM material, post-harvest monitoring, reports and records forms.

3.0 INSPECTION TIMING AND NOTIFICATION

3.1 Timing

The timing of inspections will be at the discretion of NBFP through the Competent Authority. Field trial inspections are usually done during site preparation, at panting, before and during flowering, post flowering, at harvest and during post-harvest monitoring. Inspection prior to flowering is recommended as it helps the Biosafety Inspectors to verify isolation distances and other measures taken to ensure reproductive isolation. This arrangement allows the Inspector to see if confinement is being followed and gives a view of surrounding crops. It is important to determine if sexually compatible crops or weeds are growing too close to the permit site. Later in the season, inspection should also be conducted during harvest of the crop to verify records/supervise the protocols. Post-harvest monitoring is crop specific and hence is planned accordingly. Documentation and facility inspections may be carried out at any time of the year regardless of the growing season. Inspections shall be carried out at

any time during working hours.

3.2 Notifying for Inspection

The NBFP through Regulatory Authority shall notify the Authorized Party about the inspection and date it is planned to take place. The Biosafety Inspectors and trial or facility manager or Authorized Party should arrange in advance a mutually agreed upon time for the visit to the site. The Biosafety Inspectors may conduct unannounced inspections and it is therefore required that the Applicant (Authorized Party) provides a site location map. Prior notification to the Authorized Party shall not be required in the cases of unannounced inspections. Apart from biosafety aspects, the Biosafety Inspectors will also oversee the compliance with technical instructions provided by the Authorized Party. At their discretion, Biosafety Inspectors may as well carryout phytosanitary inspections.

4.0 PREPARING FOR INSPECTIONS

Biosafety inspectors must prepare themselves in advance of any inspection by having the appropriate documents and equipment required to carry out the inspection. Prior to actual inspection, the Biosafety Inspectors may conduct pre-inspection, which aims at preparing Inspectors for the actual inspection of the confined field trial. Pre-inspection is carried out one week before traveling to the trial site. For both pre-inspection and actual inspection, the inspector is advised to assemble and familiarize herself/himself with the following documents prior to a site inspection or visit:

1. Inspector’s credentials
2. A copy of Authorization from Regulatory Authority
3. Site location map
4. Important document to show the nature and the origin of the plant material
5. Contact address of the Authorized Party
6. Copies of the practical manual for safe conduct of confined field trials

7. Forms and notebook needed for data collection at the trial site
8. Letter of notification made to the Authorized Party or Trial Manager for announced inspection
9. Reports of previous inspections if available
10. Compliance history of the Authorized Party if applicable
11. Additional, specific terms and conditions for the confined field trial to be inspected

In addition to the documents indicated above, Biosafety Inspectors may find it useful to take with them some or all of the following equipment:

1. A Global Positioning System (GPS) unit
2. A camera
3. A timing device
4. A measuring tape or measured rope appropriate to verify isolation distances
5. Transport to and from the site
6. Any other equipment deemed necessary depending on the nature of field trial

5.0 THE INSPECTION PROCESS

A typical site inspection is carried out in the following steps:

- Biosafety Inspectors familiarize themselves with the biosafety requirements and technical aspects of the regulated activity (trial)
- For announced inspections, the inspector arranges the site visit with the Authorized Party and finds out who will host the inspection at the site
- In case the inspector has any questions concerning the practical manual for safe conduct of confined trials, the specific Terms and Conditions of the trial, or any other technical aspect of the crop, trait, or trial, these should be clarified before the site visit
- On arrival at the site, the Biosafety Inspector conducts a brief interview with the

Authorized Party or site manager in order to be updated on progress of the regulated activity and any areas of question or concern

- The Biosafety Inspector conducts a visual examination of the site, facility or regulated activity and takes note of compliance with requirements. Information shall be recorded in forms but the Biosafety Inspectors may as well note down more information in a notebook or record it using equipment such as video camera
- The Biosafety Inspector reviews documents and files, noting adherence to trial requirements and the practical manual for safe conduct of confined trials
- The Biosafety Inspector interviews the Authorized Party or site manager or any other personnel involved in the trial and if deemed necessary, people living or conducting activities in close proximity with the site of regulated activity. These interviews are conducted in order to clarify points and questions and also capture concerns from different stakeholders in the trial site neighbourhood. *Note that steps 4 to 7 may be completed in any order, and each may be repeated as needed*
- The Biosafety Inspector completes the forms, noting any concerns or issues
- The Biosafety Inspector conducts and exit meeting with the Authorized Party or site manager and points out any findings or areas of concern, answers any questions and advises the Authorized Party or site manager on follow-up steps and on any upcoming compliance requirements. The meeting may come up with suggestions on the way forward that shall be confirmed after consultation with the Regulatory Authority
- In the case of significant findings of non-compliance and when immediate action is needed, the Biosafety Inspector reports to Regulatory Authority orally within 24 hours, while the Inspector is still at the site. A written report about the incident will follow this oral report. The Regulatory Authority shall contact both the Trial Manager or any other responsible person and the Authorized Party immediately for a corrective action as appropriate.
- The Biosafety Inspector should complete a report on the inspection and forward

it to the Regulatory Authority within three working days after returning to workplace.

- All notes, checklists, record forms, other documentations made at the site and submitted reports are securely kept by the Biosafety Inspector for as long as necessary

Note that in some cases, certain action may be taken by the Biosafety Inspector upon noticing breach of the terms and conditions at the site. However, confirmation on the way forward shall be obtained after consultation with the Regulatory Authority. Note further that inspections for compliance are carried out on an activity-by-activity basis and crop-by-crop cases. Inspectors shall make notes of issues that need more clarification during inspection while taking records as outlined in the Record forms.

6.0 CRITICAL ASPECTS OF INSPECTIONS

6.1 Facilitation of inspectors

The Regulatory Authority is required to facilitate Biosafety Inspectors or any contracted parties that shall be conducting biosafety inspections

6.2 Facility and records inspection at the trial site

Inspection of the facility and records may be carried out in advance of the trial as a condition of approval, or at any time once a facility is registered for GM plant activity. The critical aspects of the facility and records are:

- Adequacy and security of the facility and trial site where GM plant material is to be stored and tested
- Adequacy and training of personnel
- Appropriateness of disposal methods
- Availability of guidance documents such as the practical manual for safe conduct of confined trials

Biosafety Inspectors shall examine the facility and records, taking note on each of the aspects outlined above

6.3 Transportation of the GM plants and products thereof

The critical aspects of compliance with procedures for shipping GM plants and products thereof are:

- Maintaining the identity of the GM plant with clear and detailed labeling
- Maintaining security and control over the material with correct packaging and documented handling

Biosafety Inspections shall conduct an examination of the facility and documents in accordance with the terms and conditions on transportation of GMOs as stipulated in the practical manual for safe conduct of confined trials and National Biosafety Guidelines for Tanzania. The Inspectors shall take note of the following:

- Packaging and labeling
- Shipping documentation
- Storage area for GM plant and products thereof
- Disposal of package and extra GM plants

6.4 Confined field trial of GM plants

The critical aspects in conducting a field trial with GM plants are:

- Maintaining security and control over the material in the field site
- Maintaining reproductive isolation
- Preventing the release of planting material from the trial site
- Completing documentation requirements so that confinement of the material may be demonstrated

Biosafety Inspectors shall conduct an examination of the trial site and documents to

ensure compliance with the terms and conditions of the approval, taking note of the following:

- Site security and trial layout
- Measures for reproductive isolation
- Documentation requirements
- Reporting requirements

6.5 Technical instructions

Technical instructions (also known as protocols) are provided by the Authorized Party. Protocols for trials typically include details that are not directly related to biosafety, but rather to the technical objectives and procedures of conducting the trial. Nevertheless, Authorized Party is required to comply with technical instructions they submitted for approval of applications. Compliance with protocols is critical in order to obtain valid, understandable and useful results, and is thus a legitimate concern of the NBFP and Biosafety Inspectors. Therefore, Inspectors shall conduct an examination of the trial site and documents in accordance with the technical instructions, taking note of the following:

- Experimental design, plot layout and labeling requirements
- Observation and sampling requirements and methodology
- Trial maintenance and monitoring requirements
- Any other technical requirements found in the technical instructions

6.6 Reproductive isolation

Maintenance of reproductive isolation is of particular importance in field trials with GM plants. For field trials, one or more of the following may be implemented to control movement of pollen from GM pants on the site to sexually compatible plants around the site:

- Isolation distances, including the timely removal of sexually compatible plants

- Border rows
- Destruction of flowers
- Tenting and bagging
- Timing of flowering
- Termination of the trial before flowering.

Biosafety inspections of field trials are frequently timed to help ensure that the Authorised Party fulfils the requirements for reproductive isolation.

6.7 Termination of confined field trial

The critical aspects of termination of a confined trial are:

- Maintaining security and control over the material in the field site
- Preventing the release of planting material from the trial site
- Appropriate measures for destruction of material in the trial site, or for storage and shipping of any material to be retained
- Completing documentation requirements so that confinement of the material may be demonstrated.

Biosafety Inspectors shall conduct an examination of the trial site and documents in accordance with the practical manual for safe conduct of field trial or other requirements, taking note of the following:

- Procedures employed or to be employed in terminating the trial;
- Measures for de-vitalization and disposal of material from the trial;
- Documentation and reporting requirements.

6.8 Post-harvest management of field trial

The critical aspects of post-harvest management of a confined field trial are:

- Maintaining control over the trial site and how it is used in post-harvest years
- Ensuring that post-harvest use is compatible with the terms and conditions of

the approval

- Monitoring for volunteers and destroying these before they flower
- Maintaining records of monitoring and actions taken when volunteers are identified

Biosafety Inspectors shall conduct an examination of the trial site and documents in accordance with terms and conditions of the approval and take note of the following:

- Post-harvest restrictions regarding ways in which the field may be used
- Post-harvest monitoring and documentation requirements.

6.9 Unintended Release

The critical aspects of effective response to any unintended release of GM plants are:

- Containing the GM plants or products thereof at the release site
- Timely communication with Regulatory Authorities
- Removing the GM plants from the site or rendering them non-viable
- Preventing GM plants from being consumed by humans or animals
- Preventing GM plants from becoming established and persisting in the environment.

Biosafety Inspectors shall review the corrective action reports related to any unintended release and confirm that the follow up actions were implemented. To handle effectively issues related to unintended release, inspectors are advised to familiarize themselves with the Manual for emergency response. An inspection of the release site may be required by the Regulatory Authority, which will provide specific requirements for such inspection, according to the characteristics of the release.

6.10 Quality of Data and Records

Keeping records of all activities related to confinement of field trial is required in order

to establish compliance with the terms and conditions of trial approval. Records could be used to find out if unintended release occurred during field trial. Thus Biosafety Inspectors shall conduct an examination of the activity documentation files and evaluate the adequacy and compliance of the documents with the terms and conditions of the approved activity. Data review helps to ensure that all documentation associated with a regulated GM plant activity is available, completed, clear and authentic.

6.11 Exit meeting

An exit meeting between the Biosafety Inspector and Authorized Party or site manager is critical to on-going education, understanding and communication about the terms and conditions for field trials of GM plant. The inspector reviews with the Authorized Party or the site manager any significant findings from the inspection, and raises any issues, concerns or questions raised by the trial personnel during the inspection.

In some instances follow up actions and responsibilities may also be discussed and recommendations reported. It may be necessary for the inspector to consult with the Regulatory Authority to determine how to proceed on some issues. In these cases the Biosafety Inspector should inform the Authorized Party that the Regulatory Authority will be in contact with them to establish what follow-up action will be required.

6.12 Inspection Report

The Biosafety Inspector shall complete an inspection report, providing a brief narrative of the inspection, noting any significant findings or areas of concern on the part of the inspector or site manager, and any follow up actions that are recommended, including recommendations for subsequent inspections. Copies of the completed inspection forms and information collected in any other form shall be part of inspection report.

The inspection report should be submitted to the Regulatory Authority within 3 working days after the inspection.

The Regulatory Authority may from time to time suggest a report format, but it should contain information on:

- The date and purpose of the inspection
- The activity's regulatory approval code
- Details on any significant findings of inspections
- Immediate actions taken by Inspector while at the trial site, if any
- Recommendations on follow-up actions
- Issues the Regulatory Authority is required to address with the Authorised Party
- The name and signature of the inspector.

7.0 INSPECTION FORMS
7.1 Facility Inspection Form

FACILITY INSPECTION FORM			
Facility address (location):			
Authorization Code Number(s), if any:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
FACILITY			
In the appropriate box, check Yes or No if inspected; check NI if not inspected		**YES**	**NO**
Is the facility secured from unauthorised access?			
Is the approval document for the facility available			
Is the facility having enough space for personnel to carry out duties relevant to the trial?			
Comments:			
STORAGE AREA			
Is the storage facility labelled as containing regulated GE plant materials			
Is the storage facility fully enclosed to limit access to authorized personnel?			
Are different samples of GE plant materials stored separately?			
Are GE plant materials and Non-GE plant material stored separately?			
Is there pest control arrangement in place?			
Is the Facility Manager maintaining the storage facility's Compliance document Binder			
Is the inventory list available and kept current for GE plant materials movement in and out of storage?			
Comments:			
PERSONNEL			
Are personnel trained on the relevant SOPs and other confined field trial requirements?			
Is there a record of staff training in the biosafety file for the facility?			
Has training been conducted within the past 1 year?, If No, when is it planned (use comment space)			
Are the biosafety SOPs current and accessible to all staff members?			
Comments:			
FIELD TRIAL SITE			
Is the location of field trial established and marked?			
Is reproductive isolation distance maintained?			
Is there arrangement for GE plant materials and other wastes disposal?			
Is site guarded all the time?			
Is the trial site fenced (a fence in good condition)?			
Any other observations			
Comments:			
Inspector Signature:	**Date:**		
Site Manager Signature:	**Date:**		

7.2 Transportation & Storage Inspection Form

SHIPPING & STORAGE INSPECTION FORM			
Storage Site Identification:			
Authorization Code Number(s):		**Trial Manager:**	
Inspector:		**Date of Inspection:**	
PACKAGING AND LABELLING			
In the appropriate box, check Yes or No if inspected; check NI if not inspected		**YES**	**NO**
Is the number of packaging layers sufficient for the material?			
Are different GE plant materials sufficiently separated in the package to prevent mixing?			
Is each layer of packaging labelled as required?			
If the packaging has not been retained, has authorization for disposal been documented?			
How was the packaging material disposed of?			
Comments:			
SHIPMENT DOCUMENTATION			
Are all Shipping Forms adequately completed, signed and dated?			
Are copies of all shipping documents available in the Compliance Document Binder?			
Comments:			
Storage Area			
Is the storage area restricted to personnel only?			
Is the area sign-posted according to requirements?			
Are GM plant materials kept separate from non-GM plant materials?			
Are GM plant materials clearly identified?			
Is there an inventory list available in the storage area for GM plant movement and is updated?			
Comments:			
Inspector Signature:		**Date:**	
Trial Manager Signature:		**Date:**	

7.3 Confined Trial Inspection Form

CONFINED TRIAL INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):		**Trial Manager:**	
Inspector:		**Date of Inspection:**	
TRIAL ESTABLISHMENT			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Do site security measures meet the requirements?			
Was all GM plant materials planted after the authorization date?			
Authorization Date:	Planting Date(s):		
Are provisions for training site personnel adequate?			
Are measures for cleaning equipment and personnel sufficient to prevent off-site movement of GM plant materials			
Has excess planting material been properly disposed of or retained in secure storage?			
Is the trial site and layout properly labelled?			
Has a Record of Planting, including a final map of the trial site, been completed and submitted to the regulatory authority? Date sent:			
Does the size of the trial fall within the requirements for this activity? Actual measurement: (…….X……) = area (m^2)			
Comments:			
REPRODUCTIVE ISOLATION			
Is the spatial isolation distance free of prohibited plants?			
Has the spatial isolation distance been monitored and documented according to requirements?			
Were all prohibited plants in the spatial Isolation distance identified and destroyed before flowering?			
List other measures for reproductive isolation that have been implemented:			
Isolation Measure	**Procedure/Equipment Required**	**In Place? (Y/N)**	
Have these additional reproductive isolation measures been monitored and the monitoring recorded?			
Comments:			
DATA COLLECTION			
Has data been collected from the trial in accordance with the protocol?			
Comments:			
Inspector Signature:		**Date:**	
Trial Manager Signature:		**Date:**	

7.4 Confined trial protocol inspection form

CONFINED TRIAL PROTOCOL INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL DESIGN AND ESTABLISHMENT			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Do the trial site layout and experimental design agree with the site map?			
Do the plots, plot layout and experimental design meet the requirements of the technical instructions?			
Are the site labels present, clear and do they meet requirements?			
Do buffers, borders and security meet requirements?			
Comments:			
DATA COLLECTION AND SAMPLING			
Have all data been collected to date, according to the trial protocol?			
Has approved sampling been carried out according to the approved methodology?			
Has any storage, transportation or analysis of samples been carried out according to the approved methodology?			
Have all reporting requirements been submitted to the Regulatory Authority?			
Comments:			
COMPLIANCE WITH OTHER INSTRUCTIONS (LIST SPECIFIC INSTRUCTIONS, ACCORDING TO TRIAL)			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

7.5 Confined trial termination inspection form

CONFINED TRIAL TERMINATION INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TERMINATION OF THE TRIAL			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Was the regulatory authority notified at least five (5) days prior to termination or harvest?			
Are measures for cleaning equipment and personnel numbers adequate to prevent the off-site movement of viable GM plant material?			
Are any GM plant materials to be retained?			
If yes, has the retention of GM plant materials been authorized by the Regulatory Authority?			
Are GM plant materials to be retained or disposed off-site?			
If yes, do measures for packaging, labelling and transport meet the regulatory requirements?			
Comments:			
DEVITALISATION AND DISPOSAL			
Are the measures in place for on-site disposal adequate?			
Describe measures for on-site disposal or de-vitalization:			
Comments:			
RECORDS AND REPORTS			
Have all relevant reports been completed and submitted to the Regulatory Authority? Date sent:			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

7.6 Trial post-harvest inspection form

TRIAL POST-HARVEST INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
POST-HARVEST RESTRICTIONS			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
What crop will be or has been grown on the post-harvest site?			
Does this crop meet the regulatory requirements?			
Does the Authorized Party retain control over the trial site for the post-harvest period?			
Are measures in place to prevent grazing on the land, if this is a requirement?			
Comments:			
POST-HARVEST MONITORING			
Is post-harvest monitoring being carried out and documented according to requirements?			
Are volunteers being destroyed and disposed of according to requirements?			
List measures for destruction and disposal of volunteers:			
Are measures in place for cleaning equipment that is used to destroy volunteers?			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

7.7 Trial Record Review and Exit Meeting Inspection Form

TRIAL RECORD REVIEW AND EXIT MEETING INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL RECORDS AND FILES			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Are copies of guidelines, SOPs, terms and conditions of authorization and other relevant documents readily available to trial personnel?			
Are trial records and files organized and stored in a secure area?			
Are trial records and files readily available to trial personnel?			
Are trial records and files complete and up-to-date?			
Are adequate recording standards being maintained?			
Have all required reports been submitted promptly?			
Are copies of all reports included in the trial files?			
Comments:			
EXIT MEETING (ATTACH ADDITIONAL PAGES IF NEEDED)			
Comments or concerns of Inspector:			
Comments or concerns of Trial Manager:			
Any follow-up actions recommended and responsibilities allocated:			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

7.8 Unintended Release & Non-Compliance Inspection Form

UNINTENDED RELEASE & NON-COMPLIANCE INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
UNINTENDED RELEASE OR NON-COMPLIANCE			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Was any unintended release recorded?			
Was any non-compliance incident recorded?			
Note: If no incidents occurred, skip the following questions and sign below.			
Briefly describe the incident:			
Where required, was the incident reported to the Regulatory Authority?			
Has corrective action been taken in accordance with the requirements?			
Describe the corrective action taken:			
Are additional follow-up measures to be carried out?			
If yes, describe:			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

7.9 Inspection Report

INSPECTION REPORT	
Trial Site Identification:	
Authorization Code Number(s):	**Trial Manager:**
Inspector:	**Date of Inspection:**

GROWTH STAGE OR TRIAL STATUS AT TIME OF INSPECTION

BRIEF NARRATIVE OF THE INSPECTION (ATTACH ADDITIONAL PAGES IF NEEDED)

ITEMS OF CONCERN, UNANSWERED, OR REQUIRING RE-INSPECTION	
Item	**Re-Inspection? (Y/N)**
Comments:	

CONCERNS OF TRIAL MANAGER AND/OR INSPECTOR

FOLLOW-UP ACTIONS RECOMMENDED, RESPONSIBILITY, AND TARGET DATE			
Follow-Up Action	**Responsibility**	**Target Date**	**Re-Inspection? (Y/N)**
Comments:			

Inspector Signature:	**Date:**
Date Submitted:	

8.0 APPENDIXES

8.1 COTTON (GOSSYPIUM SPP) (TPRI/CS-COT-SOP/2004)

a) Requirements for planting of field trials

The Inspector shall verify records where necessary and make note of the following:

- ✓ Does the Authorized Party have an area designated to clean the machinery that may contain seeds or reproductive parts?
- ✓ Was all equipment used to seed or plant Regulated GE plants were free of all plant materials before entering the trial site, including seed and vegetative material that may be present from prior operations .
- ✓ Does all equipment used to seed or plant Regulated GE plants material or in the maintenance of the trial site cleaned on the trial site and by which method? (Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water) .
- ✓ Were any residual plant material recovered during the process of cleaning field equipment destroyed and if so, by which method? (crushing, deep burial, discing into the soil, burning, or treatment with appropriately labelled herbicides and/or chemicals) and were they disposed of on the trial site? If seeds or reproductive parts were washed off the equipment, did the Authorized Party have a way to ensure that they do not survive? How?
- ✓ Does the Authorized Party have the necessary equipment to destroy the plant material as described in their protocols (e.g., an autoclave, steamer, burial pit, incineration, etc.)?
- ✓ Was the map of the trial site prepared by the Trial Manager within 48 hrs of completion of planting and appended to the Record of Planting? (Instructions for the preparation of maps are provided in Annex 1) .
- ✓ Was a Record of Planting completed for each field trial site? and was a copy of

the Record of Planting with a map, submitted to each of TPRI and the Authorized Party within 5 working days of planting, and the original retained by the Trial Manager in the Compliance Document Binder?

b) Requirements for SOPs of field trials of Regulated GE cotton

Inspector shall verify records and make note of the following:

- ✓ Were all four corners of each trial site clearly marked with permanent markers suitable to permit identification of the trial site during both the growing season and the mandated period of post-harvest land use restriction (e.g. fence post, PVC piping) .
- ✓ If GPS coordinates was used to record at all four corners of each trial site it should have accuracy of at least plus or minus 2 m .
- ✓ Are all field trial sites of Regulated GE plants reproductively isolated from any prohibited plants that are not part of the trial by one or any appropriate combination of the methods described in the SOP *(TPRI/CS-COT-SOP/2004)?*

✓ Was a single field trial site reproductively isolated entirely by no less than one continuous method of reproductive isolation?

c) Spatial isolation

Spatial isolation of field trial sites of Regulated GE Cotton plants

Inspector shall verify records and make note of the following:

✓ Were the Trial sites of Regulated GE plants spatially isolated from other prohibited plants *(e.g.,* G. *hirsutum and* G. *barbadense)* by a minimum isolation distance of 400 m?

- ✓ Was the isolation distance kept free of all cotton plants, including volunteers and prohibited plants, by implementing which program? (E.g. program of regular inspection and rouging *TP RI/CS-COT-SOP/2004).*
- ✓ Were any cotton plants or prohibited plants in the isolation distance removed before anthesis? Were there any cotton plants or prohibited plants within the isolation distance permitted to complete anthesis? If so, a breach of reproductive isolation will have occurred. It must be reported to TPRI Regulatory Authority orally within 24 hours.
- ✓ If prohibited plants were removed from the isolation distance, how were they destroyed? (rouging, crushing, deep burial, discing into the soil, burning, or treatment with appropriately registered herbicides and/or chemicals) and disposed off on site how?

d) Isolation of field trials of Regulated GE plants with border rows

If the Authorized Party's protocols use border rows, check for the thickness of border rows

The Inspector shall verify records and make note of the following:

- ✓ If the field trials of Regulated GE plants are reproductively isolated from other cotton plants by planting a 12 m wide, uninterrupted perimeter border row of non-transgenic cotton plants at a planting density comparable to the Regulated GE plants
- ✓ Check that the non-transgenic border rows are planted with a cotton plants variety that will mature concurrently with the Regulated GE plants and are managed using standard agronomic practices .
- ✓ Is the growth stage of the border row plants equivalent to the growth stage of the trial plants?
- ✓ Is the anthesis of Regulated GE plants concurrent with anthesis of cotton plants in

the border row? Is the Trial Manger implementing a program of regular inspection *(TP Rf/CSCOT-SOP/2004)?*

- ✓ Verify if any trial plants begin flowering prior to the guard row or continue flowering after the guard row plants have finished flowering, if so, a breach of reproductive isolation will have occurred and shall be re-established by spatial isolation where the conditions for spatial isolation can be met (see *TPRf/CS-COT-SOP/2004).* The Inspector shall report orally to TPRI Regulatory Authority within 24 hours .
- ✓ Verify if the integrity of the border row is compromised and cannot be re-established, a breach of reproductive isolation will have occurred and shall be re-established by spatial isolation where the conditions for spatial isolation can be met (see *TPRf/CS-COTSOP/2004).* The Inspector shall report orally to TPRI Regulatory Authority within 24 hours.
- ✓ Where reproductive isolation of the Regulated GE plants cannot be re-established by spatial isolation, the Inspector shall report orally to TPRI Regulatory Authority within 24 hours for instructions on the corrective action to be taken.

e) Early Crop Destruct may be used as an alternative method of reproductive isolation

The intention for application of this method must be mentioned in the application for approval. Early Crop Destruction/harvesting of Regulated GE plants shall be conducted in the trial site prior to emergence of inflorescence (flowers). Early Crop Destruct may be conducted after getting an authorization from TPRI.

Inspector shall verify records and make note of the following

The Authorized Party shall inform TPRI in writing 2 weeks before the intended date of early crop harvest/destruction. TPRI Inspector will supervise the process of early harvest/destruction of the Regulated GE plants in the trial site .

f) Monitoring of the field trial by the Trial Manager

Inspector shall verify records and make note of the following:

- ✓ The Inspectors shall verify records if the Trial Manager, or a person so designated for this purpose by the Trial Manager, monitors and make note of the trial site every 2 weeks from the time of planting until the time of harvest.
- ✓ Verify if the Record of Spatial Isolation (TPRI/SI-COT/R/2004) are used to document all monitoring activities needed to ensure spatial reproductive isolation of the trial site .
- ✓ Verify where spatial isolation is used for reproductive isolation, the growth stage of any prohibited cotton plants were recorded during inspection based on the Cotton Growth Stage Key (see Annex 2) .
- ✓ Verify when reproductive isolation is achieved using border rows, inspection of cotton plants in trial and in the border rows were undertaken every week from the time the first inflorescence emerges on the first bloom until the termination of pollen shed by the Regulated GE plants. Following inflorescence emergence and until all Regulated GE plants have completed anthesis, trials were inspected daily .
- ✓ Verify if the Record of Border Row Isolation *(TP RI/BRI-R/2004)* was used to document all inspection activities needed to ensure reproductive isolation of the trial site with guard rows .
- ✓ Where border rows were used for reproductive isolation, the growth stage of Regulated GE plants and border row cotton plants were recorded during inspection based on the Cotton Growth Stage Key (see Annex 2) .

g) Occurrence of non-compliance

Inspector shall verify records and make note of the following:

- ✓ Verify if the Trial Site Manager and/or the Authorized Party notified TPRI immediately of all situations where reproductive isolation of the trial site were breached (notification process is as 9.2, *TPRI/CS-COT-SOP/2004)*
- ✓ Verify if there was any accidental release at any location, and if the Trial Manager and/or the Authorized Party immediately notified TPRI orally, and confirmed such in writing within 24 hours. Did TPRI take action appropriately?

h) Corrective action in the event of an accidental release

The Inspector shall verify records of the following activities if applicable: In the case of noncompliance, the Inspector shall immediately notify the TPRI Regulatory Authority to determine the subsequent course of action.

- ✓ Was there any event of any accidental release from a trial site, and were there any attempts made to recover the Regulated GE plants and destroyed.
- ✓ If an accidental release affected an area outside the perimeter of the trial site, was that location marked and treated in the same manner as the trial site with respect to ensuring that no additional release of material occurred?
- ✓ Was there any accidental release at any location, and did the Trial Manager and/or the Authorized Party immediately within 1 hour notify the Authorized Party and the TPRI Regulating Authority in writing within 24 hours of the accidental release.
- ✓ Was the accidental release of a Regulated GE plants immediately documented in a Record of Corrective Action. Was the original Record retained by the Trial Manager, and copies submitted by facsimile to TPRI and the Authorized Party?

i) Record keeping

- ✓ If the Record of Planting and map for each trial site were retained by the Trial Manager in the Compliance Document Binder and one copy submitted to each of TPRI and the Authorized Party within 48 hours of planting.
- ✓ If the Record of Spatial Isolation for each trial site was retained by the Trial site Manager in the Compliance Document Binder.
- ✓ If the Record of Guard Row Isolation for each trial site was retained by the Trial Manager in the Compliance Document Binder.
- ✓ If the Compliance Document Binder was available for inspection by TPRI regulatory officials.

The Inspector conducting the above activities shall sign all the applicable documents after completion of the inspection.

8.2 INSPECTION OF CURRENT SEASON FIELD TRIAL OF REGULATED GENETICALL Y ENGINEERED (GE) MAIZE (ZEA MAYS) (TPRI/CS-MZ-SOP/2004)

Inspection of the current season field trials Regulated Genetically Engineered Maize *(Zea mays)* to ensure compliance with the SOPs. The SOPs are conditions that must be met in order to assure containment of the field test of GE plants.

Verify if the Authorized Party, his/her employees and all other agents acting on behalf of the Authorized Party have received training from TPRI on compliance of this SOP.