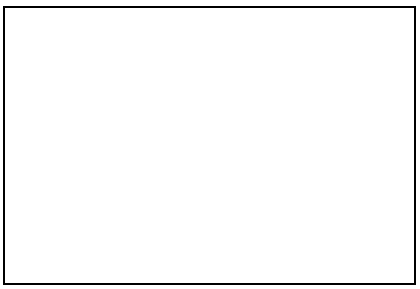
ENVIRONMENTAL AFFAIRS DEPARTMENT

Biosafety Inspection Manual for field experiments involving Genetically Modified Plants

Inspectors' Handbook



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Acknowledgements

(For later action)

Acronyms

ABBC Agricultural Biosafety Biotechnology Committee

CFT	Confined Field Trial
DNA	Deoxyribonucleic Acid
EAD	Environmental Affairs Department
GE	Genetic Engineering
GM	Genetic Modification
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
LMO	Living Modified Organism
NA	Not Applicable
NBRC	National Biosafety Regulatory Committee
NI	Not Inspected
NRCM	National Research Council of Malawi
PBS	Program for Biosafety Systems
SOP	Standard Operating Procedures

Glossary

Anthesis: The time when a flower, plant or crop releases pollen.

Applicant: A party submitting an Application for a confined field trial.

Authorized Party: This is the addressee of the Letter of Authorization. The Authorized Party shall be a permanent resident of this country, or shall designate an agent who is a permanent resident. 'Authorized Party' is construed herein to include any designated agents thereof.

Authorization Number: A reference code or number given by the Biosafety Registrar to the application and CFT permit once granted to the applicant.

Compliance: Fulfilling the requirements of the Terms and Conditions of Authorization, especially with regard to confinement measures.

Compliance Infraction: Violation of the Terms and Conditions of Authorization.

Confined Field Trial (CFT): This is a field trial of GM plants not approved for general release, in which measures for reproductive isolation and material confinement are enforced in order to confine the experimental plant materials and genes to the trial site. These trials/experiments provide researchers with important information on environmental interactions and agronomic performance of the crop in a safe and controlled manner.

Confinement: Restriction of an organism and its genetic traits to a specific and defined area of the environment, herein called the 'confined field trial site' or the 'trial site'.

Construct: An artificially constructed segment of DNA to be transferred into a cell or tissue in the process of genetic modification.

Event: A single instance of modification of a specific plant species and type using a specific genetic construct.

Facility Manager: The individual responsible for the supervision of storage or testing facilities.

Following Crop: A crop planted on a trial site after harvest or termination of a confined field trial.

Free-Living: A plant living outside cultivation, or surviving without human intervention.

Genetic Confinement: ???

Genetic Engineering/Genetic Modification: The genetic modification of organisms by recombinant-DNA techniques.

Genetically modified organism GMO) or Genetically Engineered organism (GEO): is an organism whose genetic material has been altered using genetic engineering techniques known as recombinant DNA technology where DNA molecules for example from different sources are combined into one molecule to create a new set of genes**.** For the purposes of this document, the terms 'genetically engineered (GE)', 'transgenic', 'genetically modified (GM)' are equivalent.

Guard Rows: A planting of the same or a different plant species around GM plants in the trial site, to serve as a means of reproductive isolation, or as a visual or physical barrier. These are sometimes called 'border rows', or 'pollen trap rows' when used for reproductive isolation.

Incident: Any occurrence that causes, or threatens to cause, a breach of confinement of GM plant material.

Material Confinement: Measures taken to ensure that GM plant material is not consumed by humans or animals and does not persist in the environment.

National Biosafety Regulatory Committee: A committee established under the Biosafety (Management of Genetically Modified Organisms) Regulations, 2007 to control and manage the utilisation of GM materials. Its mandate is to evaluate all applications concerning genetically modified organisms and advise the Minister responsible for matters related to genetic modification of organisms.

Pollen-Mediated Gene Flow: The transfer of genes from one plant to another in pollen by successful fertilization.

Prohibited Plants: Plants that are sexually compatible under natural conditions with the GM plants being grown under confinement, and are thus prohibited from the established spatial isolation distance of a confined field trial.

Propagative Plant Material: Plant material such as seeds or cuttings capable of establishing and surviving in the natural environment without human intervention.

Regulatory Authority: The government body having the statutory authority to regulate an activity.

Regulated: As used here, a GMO that has not been approved for unrestricted release.

Reproductive Isolation: Measures taken to prevent, principally, pollen-mediated gene flow from plants in the trial site to nearby sexually compatible species, also known as 'genetic confinement'.

Sexually Compatible: Capable of cross-pollinating and forming viable hybrids without human intervention.

Spatial Isolation: A method of achieving reproductive isolation by separating plants in the trial site from prohibited plants by a defined distance.

Study Plan: Also known as the 'Protocol', the Study Plan establishes the technical objectives and required methodology of the trial, beyond those requirements related to confinement.

Temporal Isolation: A method of achieving reproductive isolation by preventing the flowering times of two crops from overlapping, usually by spacing out the planting dates.

Transgene: The gene or genetic material introduced into a plant by genetic enginnering

Trial Manager: The individual at a particular trial site, designated by the Authorized Party or Principal Investigator as responsible for management and compliance of an authorized confined field trial. Trial Managers are authorized to complete and sign documentation, forms and notes applicable to the trial.

Trial Site: The area of a field trial that is confined by one or more continuous methods of reproductive and/or material isolation. It is sometimes called Study Area.

Trial Site Identification: A descriptive or numeric identifier for a single Trial Site, which may include multiple events, constructs, and/or Authorization Numbers.

Volunteers: Progeny arising from the GM crop within a confined field trial site.

1.0 Introduction

For the benefits of new technologies such as Genetic Modification (GM) crops to be made available to the citizens of this country, these technologies must be evaluated realistically in confined field trials (CFTs). It is only through these trials that the true benefits, as well as potential drawbacks, of new agricultural technologies can be discovered, and a basis established for their general use. These trials must, however, be conducted in a way that ensures that no harm to the environment, people or animals comes about as a result.
This Manual is intended as a resource for use by Biosafety Inspectors and others designated by the Regulatory Authority to inspect or oversee confined field trials or facilities for compliance with the applicable national guidelines.
Biosafety in the conduct of confined field trials is ensured by adherence to the requirements found in several types of documents:

1.1 Standard Operating Procedures (SOPs), such as those found in the Trial Manager's Handbook, give specific instructions to field trial personnel for managing GM plants and plant products in the following areas:
   (a) Data Quality and Integrity
   (b) Shipment and Storage
   (c) Trial Conduct
   (d) Sampling
   (e) Termination
   (f) Post-Harvest Management
   (g) Reporting
   (h) Incidents and Contingency Planning

1.2 This Inspector's Manual, which is a companion booklet to the Trial Managers Handbook, provides instructions for Biosafety Inspectors and other designated agents of the Regulatory Authority for inspection and oversight of confined trials.
1.3 Terms and Conditions of Authorization for conduct of a specific trial, issued by the Regulatory Authority upon approval of a specific trial.
1.4 The Study Plan, which contains technical instructions for the conduct of a specific trial, provided by the Authorized Party to trial personnel.
1.5 Guidance Documents, which provide informal instructions from the Regulatory Authority on management of GM testing for Applicants and Authorized Parties.

Individuals inspecting CFTs must be familiar with all of these documents in order to fully comprehend and discharge their duties in an effective manner. It is especially critical that Inspectors have complete command of the requirements found in the Terms and Conditions of Authorization issued by the Regulatory Authority for a specific trial, and the SOPs providing guidance for trial conduct. The requirements found in these documents are the foundation for biosafety in the conduct of confined field trials, and form the basis of the inspection procedures outlined in this manual.

An Inspector or other official will be questioned about the basis, exact meaning and interpretation of these requirements by trial personnel. Careful responses founded on outstanding knowledge are critical to building understanding and fostering self-compliance in Principal Investigators, Trial Managers and other trial personnel, and in ensuring biosafety in testing of GM plants. It should be well-noted by Inspectors and other responsible parties that the Terms and Conditions of Authorization for a particular trial are the governing document

for that trial, should there be any conflict or inconsistency with other published requirements. Typically, individuals routinely inspecting GM trials will be provided with specific training in all aspects of biotechnology, biosafety and specific procedures as relevant to those trials or activities for which they have oversight responsibility.

Procedures for the conduct of confined field trials are intended to accomplish three important goals:

(a) preventing the escape from the trial site of novel genes in pollen, seed or other plant parts;
(b) preventing GM plant material from being consumed by humans and/or animals;
(c) Preventing GM plants from escaping from confinement and establishing and persisting in the environment.

With the achievement of these goals, novel genes and their products may be confined to the field trial site, and their release into the general environment prevented.
It is the responsibility of the Authorized Party to ensure compliance with the Terms and Conditions of Authorization, and this responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of conducting confined trials. Similarly, the responsibility of the Authorized Party and its employees is not limited to the fulfilment of these procedures in achieving the goals of confinement outlined above; they are required to take all reasonable steps to achieve these goals.

Biosafety is a primary goal of the Regulatory Authority, and is best served when all requirements and procedures are clearly known in advance by the responsible parties. Clear and established procedures, on-going education and oversight, and clear communication are the cornerstones of a productive working relationship between Regulators and trial personnel, serving the goals of safe and productive testing of GM crops for the benefit of this country and its citizens.

2.0 Objective

The main objective of this manual is to provide instruction and guidance to Inspectors of confined field trials. This Manual provides a basis for a logical and step-wise approach to preparing for inspection, conducting inspection of the field site and documentation, interviewing field personnel for pertinent information, obtaining necessary confirmation of key information, writing the inspection report, notifying the Regulatory Authority of inspection results and findings, and implementing any corrective actions that may be required resulting from the inspection.

Strict adherence to procedures and requirements for the confinement of GM plants and plant products is critical in safeguarding regulated GM material, preventing the release of the material into the general environment, and preventing any unauthorized material from being used as food or feed.

Inspection and oversight for confined trials serve as a means of verifying whether compliance with requirements for the following are met:

(a) Facilities and records
(b) Shipping/Storage/Disposal after planting of GM Plants and Plant Products
(c) Confinement of field trials with GM plants

3.0 Preparing for Inspection

Timing of standard inspections should be planned in advance of the trial based on the specific CFT,and is typically based on crop-growth stage, progress or status of the trial, or upon specific request from the Biosafety Registrar. 'Critical Stages' at which an inspection may be targeted are: planting, prior to flowering, during flowering, at harvest, and during post-harvest monitoring. Inspection prior to flowering of the experimental GM crop is always recommended, so that isolation distances and other measures of reproductive isolation may be verified. An inspection of the Applicant's proposed facility and records may also be required as a condition of approval of a CFT application.

In addition to biosafety, the Inspector may also verify compliance with requirements found in the Study Plan or technical instructions provided by the Authorized Party to trial personnel. Authorization to conduct a CFT does not exempt the Authorized Party from phytosanitary requirements.

The Inspector must prepare him/herself in advance of any inspection—both mentally, and by obtaining the appropriate documents and equipment required to carry out the inspection. The Inspector shall assemble, and be familiar with, the following documents prior to a site inspection or visit:

(a) copy of the Letter of Authorization, including the specific Terms and Conditions of the trial;
(b) Import documents to show the nature and origin of the trial
(c) Site location map;
(d) Contact details of the Trial Manager and/or Authorized Party;
(e) Copies of relevant SOPs being used at the site or facility;
(f) A copy of this manual and Inspection Checklists, a clipboard, notepaper/notebook and pens;
(g) A copy of the Study Plan for the trial to be inspected and /or technical instructions from the authorised party or principal investigator;
(h) Any additional technical information that may be needed, for example: crop growth stages, a list of pesticides approved for use in the crop, etc;
(i) Previous inspection reports for the site to be inspected, if available.

Inspection can be carried out any time. When inspections are scheduled in advance, the Authorized Party should also be notified of the upcoming visit. The responsible IBC may be informed.

Unannounced inspections may be carried out at any time at the discretion of the Regulatory Authority, without prior notification of the Authorized Party or Trial Manager. Inspections may be carried out at any time during working hours. The Trial or Facility Manager must provide access to the trial site and storage area, and must make records available for the purpose of inspection by the Regulatory Authority's Inspectors and other designated agents.
In addition to the documents required for any site visit, depending on the circumstances certain facilities, equipment and /or information may also be helpful but not limited to the ones listed below:

(a) A Global Positioning System (GPS) unit;

(b) A camera;
(c) A timing device;
(d) A measuring tape or measured rope appropriate to verify isolation distances;
(e) Inspector's credentials ;
(f) Transport to/from the site;
(g) Other equipment or resources at the discretion of the Inspector.

4.0 The Process of Inspection

Before the trial begins, the Biosafety Registrar in consultation with the Chair person Of NBRC shall designate one or more individuals to be responsible for inspections during the course of the field trial.

A standard field site inspection is conducted in the following steps:

(a) The Inspector prepares him/herself for the Inspection by becoming familiar with the biosafety requirements and technical aspects of the trial
(b) The Inspector shall arrange the visit with the Trial Manager. If the inspector has any questions concerning the SOPs, the specific Terms and Conditions of the trial or any technical aspects of the crop, trait or trial, these questions should be clarified before the site visit.
(c) Upon arriving at the site, the Inspector conducts a brief interview with the Trial Manager, in order to be updated on trial progress and any areas of question or concern. The inspector can also inform the Trial Manager about the equipment he has carried for the purpose of inspection
(d) The Inspector conducts a visual examination of the site, facility or processes being inspected, and takes careful note of compliance with requirements, using the relevant checklists or notes.
(e) The Inspector reviews documents and files, noting adherence to trial requirements and SOPs.
(f) The Inspector interviews the Trial Manager or other trial personnel, if needed, to address any questions or points of clarification. *Note that steps e, and f may be completed in any order, and each may be repeated as needed.*
(g) The Inspector completes a draft of the checklists, noting any concerns or issues.
(h) The Inspector conducts an exit interview with the Trial Manager, pointing out any findings or areas of concern, answering any questions, and advising the Trial Manager on follow-up steps and any upcoming compliance requirements.
(i) The Inspector completes a report on the inspection and forwards it to the Biosafety Registrar within five working days after returning to his/her workplace. Reports shall be made in duplicate; one to be submitted to the Biosafety Registrar and the other to be retained by the inspector.
(j) In the case of significant findings of non-compliance, the Inspector shall inform the Trial Manager, the Authorised party, and the Biosafety Registrar immediately, preferably while still at the site. A written communication to the Biosafety Registrar should be submitted within 24 hours. The NBRC Secretariat shall determine an appropriate course of action and communicate requirements to the Trial Manager and/or any other responsible persons, as well as the Authorized Party and/or any other responsible persons.
(k) All notes, checklists and submitted reports shall be maintained by the Inspector in secure storage.

5.0 Critical Aspects of Inspection

Critical elements of inspection for each aspect of a confined field trial are detailed in this section, and are functionalized by the associated checklists found at the end of the Manual. Checklists are provided to support typical requirements for each aspect of compliance, and are intended to be customized to account for specific requirements of a particular trial or site.

5.1 Inspection of Facility and Records at Trial Site

Inspection of the facility and records may be required in advance of the trial as a condition of approval, or at any other time during the trial and post-harvest period. The critical aspects of the facility and records of a site where GM plant material is to be stored or tested are: adequacy and security of the facility and storage area; adequacy and training of personnel; and adequacy of the proposed trial site. Inspectors shall conduct an examination of the facility and records, taking note of specific requirements in the above areas (See Form 1).

5.2 Shipping/Storage/Disposal of GM Plants and Plant Products

The critical aspects of compliance with procedures for shipping GM plant material are: maintaining security and control over the material; maintaining the identity of the material; and completing documentation requirements so that security, control and identity of the material may be demonstrated (See Form 2).
Inspectors shall conduct an examination of the facility and documents in accordance with the SOP, taking note of the following:

(a) Packaging and labelling;
(b) Shipping documentation;
(c) The storage area for GM material.
(d) Disposal of package and extra GM material

5.3 Confinement of Field Trials with GM Plants

The critical aspects of confinement for a trial site with GM plants are: maintaining security and control over the material in the trial site; maintaining reproductive isolation of the trial site; preventing the release of propagation plant material from the trial site; and completing documentation requirements so that confinement of the material may be demonstrated (See Form 3).

Inspectors shall conduct an examination of the trial site and documents in accordance with the SOP, taking note of the following:

(a) Site security and trial establishment;
(b) Measures for reproductive isolation;
(c) Monitoring, documentation and reporting requirements.

5.4 Technical instructions for Confined Field Trial

Technical instructions for confined field trial, from the Authorised Party typically include details that are not directly related to biosafety, but rather to the study plan and technical objectives and methodology of the trial. However, compliance with technical instructions is

critical to obtaining valid, understandable and useful results, and is thus a legitimate concern of the NBRC and Biosafety Inspectors. (See Form 4)

Inspectors shall conduct an examination of the trial site and documents in accordance with the Study Plan, taking note of the following:

(a) Experimental design, plot layout and labelling requirements;
(b) Observation and sampling requirements and methodology;
(c) Trial maintenance and monitoring requirements;
(d) Any other technical requirements found in the Study Plan.

5.5 Termination of Confined Field Trial

The critical aspects of termination of a confined trial are: maintaining security and control over the material in the trial site; preventing the release of propagative plant material from the trial site; approved measures for destruction of material in the trial site, or for storage and shipping of any material to be retained; and completing documentation requirements so that confinement of the material may be demonstrated (See form 5).

Inspectors shall conduct an examination of the trial site and documents in accordance with SOPs or other requirements, taking note of the following:

(a) Procedures employed or to be employed in terminating the trial;
(b) Measures for devitalisation and disposal of material from the trial;
(c) Documentation and reporting requirements.

5.6 Post-Harvest Management of Confined Field Trial Site

The critical aspects of post-harvest management of a confined trial are: maintaining security and control over the trial site; preventing the release of plant material from the trial site into human or animal food or feed; and identifying and destroying volunteers at the trial site (See form 6)

Inspectors shall conduct an examination of the trial site and documents in accordance with SOPs or other requirements, taking note of the following:
(a)Post-harvest restriction requirements;
(b) Post-harvest monitoring and documentation requirements.

5.7 Incidents Related to from the Confined Field Trial

The critical aspects of effective response to any incidents involving GM plant material are: preventing the release of GM plant material into the general environment; preventing GM plant material from being consumed by humans or animals; and preventing GM material from establishing and persisting in the environment.

Inspectors typically review the documentation related to any incident, taking note of the response, follow up actions and documentation of the incident. An inspection of the site of

the incident shall be required by the Biosafety Registrar, which will provide specific requirements for such inspection, according to the characteristics of the incident. (See Form 7)

5.8 Inspection Report of Confined Field Trial or Facility

The 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 Trial Manager, and also any agreed follow up actions, including any need for re-inspection. Attach copies of all applicable Inspection Records to the Inspection Report (See Form 8).

5.9 Review of Trial Records and exit Interview)

An exit interview with the Trial Manager is critical to on-going education, understanding and communication. The Inspector shall review with the Trial Manager(s) any significant results or findings from the Inspection, and shall note any issues, concerns or questions raised by the trial personnel. Agreed follow up actions and responsibilities shall also be noted. (See Form 9)

The Inspection Report shall be submitted to the Biosafety Registrar within 5 working days after the Inspector has returned to his/her workplace. The report shall be submitted to the Regulatory Authority as follows:

The Biosafety Registrar
Environmental Affairs Department
Lingadzi House
P/Bag 394
Lilongwe 3.

Telephone: + 265 (0) 1 771 111
Facsimile: +265 (0) 1 773 379
Email: eadinfo@sdnp.org.mw
Website: www.malex.org.mw

6.0 FORMS FOR INSPECTION REQUIREMENTS

BIM FORM 1: Facility and records inspection at Trial site

FACILITY AND RECORDS INSPECTION – INSPECTION RECORD		
Trial Site or Facility:		
Authorization Permit Number:	**Manager:**	
Inspector:	**Date of Inspection:**	
FACILITY		
Tick Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Can the facility be secured from unauthorized access?		
Is there sufficient space and equipment for personnel to discharge duties relevant to the trial?		
Comments:		
STORAGE AREA		
Can the storage facility be secured from unauthorized access?		
Is there sufficient space in the storage facility for GM and non-GM materials to be kept separate?		
Is the storage facility adequate to protect GM material from theft, and from damage due to natural causes or animals such as rodents?		
Is there a current inventory list available for GM material in storage?		
Comments:		
PERSONNEL		
Are the number of personnel on-site/planned adequate?		
Do all Trial Managers [those authorized to sign documents for trial] have a current Training File?		
Have all Trial Managers been recently trained [within the past 1 year] on the relevant SOPs and other trial requirements?		
If no, is a date for this training planned? If planned, when: *Note: If training has not yet been carried out, a re-inspection of training documentation is required after the planned training date. This must be noted in the Inspection Report.*		
Comments:		
PROPOSED FIELD TRIAL SITE		
Is the location of the proposed field trial site established and marked?		
Is the field trial site adequately prepared at this time to commence the trial? *Note 'yes' if adequate at this time, or comment on specific deficiencies. If any deficiencies are noted, a re-inspection is required. This must be noted in the Inspection Report.*		
Fencing in place and secure?		
Provision for security guards?		
Reproductive isolation distance appears to be adequate and enforceable?		
Resources in-place or planned to carry out other measures of reproductive isolation?		
Necessary equipment available?		
Provision for disposal of material in place or planned?		
Other (describe):		
Comments:		
Inspector Signature:	**Date and stamp:**	

BIM FORM 2: Shipping, Storage and disposal of GM Plant Materials

SHIPPING & STORAGE OF PLANT MATERIAL – INSPECTION RECORD		
Trial Site Identification:		
Authorization Permit number:	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
PACKAGING AND LABELLING		
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Is the number of packaging layers sufficient for the material?		
Is each layer of packaging sufficient to prevent loss?		
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 and remaining GM material disposed off?		
Comments:		
SHIPMENT DOCUMENTATION		
Are all Shipping Forms adequately completed, signed and dated?		
Are copies of all shipping documents available in the trial file?		
Comments:		
STORAGE AREA		
Is the storage area restricted to authorized personnel only?		
Is the area sign-posted according to requirements?		
Are GM plant materials kept separate from non-GM materials?		
Are GM plant materials clearly identified?		
Is a current inventory list available for GM materials in the storage area?		
Comments:		
Inspector Signature:	**Date and stamp:**	

BIM FORM 3: Confinement of Field Trials with GM Plants

CONFINEMENT OF FIELD TRIALS WITH GM PLANTS			
Trial Site:			
Authorization Permit number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL ESTABLISHMENT			
Unless otherwise noted, tick Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Are site fences and security measures sufficient to meet requirements?			
Was all GM material planted after the authorization date in the Terms and Conditions?			
Authorization Date:	Planting Date(s):		
Are provisions for training site personnel adequate?			
Are measures for cleaning equipment and personnel adequate to prevent off-site movement of GM material?			
Has excess planting material been disposed of properly or retained in secure storage?			
Do measures for identification/labelling of trial site and plots meet requirements?			
Has a Record of Planting, including a final map of the trial site prepared according to requirements, been completed and submitted to the Regulatory Authority within five (5) days after planting?			
Does the size of the trial area meet requirements (not larger than permitted)? Actual measurement:_____ m X _____ m = _____ square meters			
Comments:			
REPRODUCTIVE ISOLATION			
Is the Spatial Isolation Distance verified to be free of Prohibited Plants at the time of inspection?			
Has the Spatial Isolation Distance been monitored and documented according to requirements?			
Were any/all prohibited plants in the Spatial Isolation Distance identified and destroyed before flowering?			
List all other measures for reproductive isolation, procedure/equipment for enforcing the measure, and whether the provisions for enforcing the measure are in place and meet requirements:			
Isolation Measure	Procedure/Equipment Required	In Place? (Y/N)	
[Ensure that the Trial Manager understands specific requirements for carrying out and documenting all measures of reproductive isolation.]			
Comments:			
MONITORING			
Has plant growth and development been monitored and documented according to requirements?			
Are target effects being monitored and documented according to requirements?			
Have any non-target effects been noted?			
If yes, have they been monitored and documented according to requirements?			
Comments:			
Inspector's Signature:	**Date and stamp**		

BIM FORM 4: Technical Instructions for Confined Field Trials

TECHNICAL INSTRUCTION FOR CONFINED FIELD TRIAL			
Trial Site Identification:			
Authorization Permit number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL DESIGN AND ESTABLISHMENT			
Tick Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Do the plots, plot layout and experimental design on the ground agree with the site map provided?			
Do the plots, plot layout and experimental design meet the requirements of the Study Plan?			
Are the plot labels and/or identification present, clear, and meet requirements?			
Do any buffers, borders and other site details meet requirements?			
Comments:			
OBSERVATION AND SAMPLING			
Have all required observations been made according to the defined methodology?			
Has any required sampling been done according to the defined methodology?			
Has any required storage, shipping or analysis of samples been carried out according to the defined methodology?			
Have all reports required by the Authorized Party been submitted according to requirements?			
Comments:			
COMPLIANCE WITH OTHER INSTRUCTIONS ***[LIST SPECIFIC INSTRUCTIONS, ACCORDING TO TRIAL]***			
Comments (Describe how the field was monitored and maintained):			
Inspector's Signature:	**Date and stamp:**		

BIM FORM 5: Termination of Confined Field Trial

TERMINATION OF CONFINED FIELD TRIAL		
Trial Site Identification:		
Authorization Permit number:	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
TERMINATION OF THE TRIAL		
Unless otherwise noted, tick Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Was the Biosafety Registrar notified at least five (5) days prior to termination or harvest?		
Are measures for cleaning equipment and personnel adequate to prevent the off-site movement of propagative GM plant material?		
Is any plant material to be retained?		
If yes, have the details of this activity been authorized by the Biosafety Registrar?		
Is any GM material to be moved off-site for disposal or retention?		
If yes, are the measures in place for packaging, labelling and transporting adequate to meet requirements?		
Comments:		
DEVITALIZATION AND DISPOSAL		
Are the measures in place for on-site disposal adequate?		
Describe measures for on-site disposal or devitalization:		
Comments:		
RECORDS AND REPORTS		
Has a Termination Report been completed and submitted to the Biosafety Registrar within ten (10) days after termination of the trial?		
Comments:		
Inspector's Signature:	**Date and stamp:**	

BIM FORM 6: Post-harvest Management of Confined Trial site

POST-HARVEST MANAGEMENT OF CONFINED FIELD TRIAL		
Trial Site Identification:		
Authorization Permit number:	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
POST-HARVEST RESTRICTION		
Unless otherwise noted, tick Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
What following crop is being grown or proposed?		
Does the following crop meet requirements?		
Does the Authorized Party retain control over the trial site for the post-harvest period?		
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 for cleaning equipment used to destroy volunteers adequate?		
Comments:		
Inspector's Signature:	**Date and stamp:**	

BIM FORM 7: Incidents Resulting from the Confined Field Trial

INCIDENT RESULTING FROM THE CONFINED FIELD TRIAL			
Trial Site Identification:			
Authorization Permit number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
INCIDENTS AND INFRACTIONS			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Any incidents noted?			
Note: If no incidents occurred, skip the following questions and sign below.			
If any serious incidents or compliance infractions have occurred or have been noted, have they been reported to the Regulatory Authority according to requirements?			
Have corrective actions been taken according to requirements?			
Are any required follow-up measures being carried out?			
If yes, describe:			
Comments:			
Inspector's signature:	**Date :**		
Trial Manager's Signature:	**Date and stamp**		

BIM FORM 8: Inspection Report of Confined Field Trial or Facility

CONFINED FIELD TRIAL OR FACILITY – INSPECTION REPORT	
Trial Site Identification:	
Authorization Permit number:	**Trial Manager:**
Inspector:	**Date of Inspection:**

CROP GROWTH STAGE OR TRIAL STATUS AT TIME OF INSPECTION

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

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

SIGNIFICANT CONCERNS OF TRIAL MANAGER AND/OR INSPECTOR

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

Inspector's Signature:	**Date and stamp**
Date Submitted:	

BIM FORM 9 : Review of Trial Records and Exit Interview

REVIEW OF TRIAL RECORDS AND EXIT INTERVIEW WITH TRIAL MANAGER – INSPECTION RECORD		
Trial Site Identification:		
Authorization Permit number:	**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 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 record keeping/documentation standards being followed adequately?		
Have all required reports been submitted promptly?		
Are copies of all reports included in the trial files?		
Comments:		
EXIT INTERVIEW (ATTACH ADDITIONAL PAGES IF NEEDED)		
Significant comments or concerns of Inspector:		
Significant comments or concerns of Trial Manager:		
Any follow-up actions agreed upon, and responsibilities:		
Comments:		
Inspector's Signature:	**Date and stamp**	