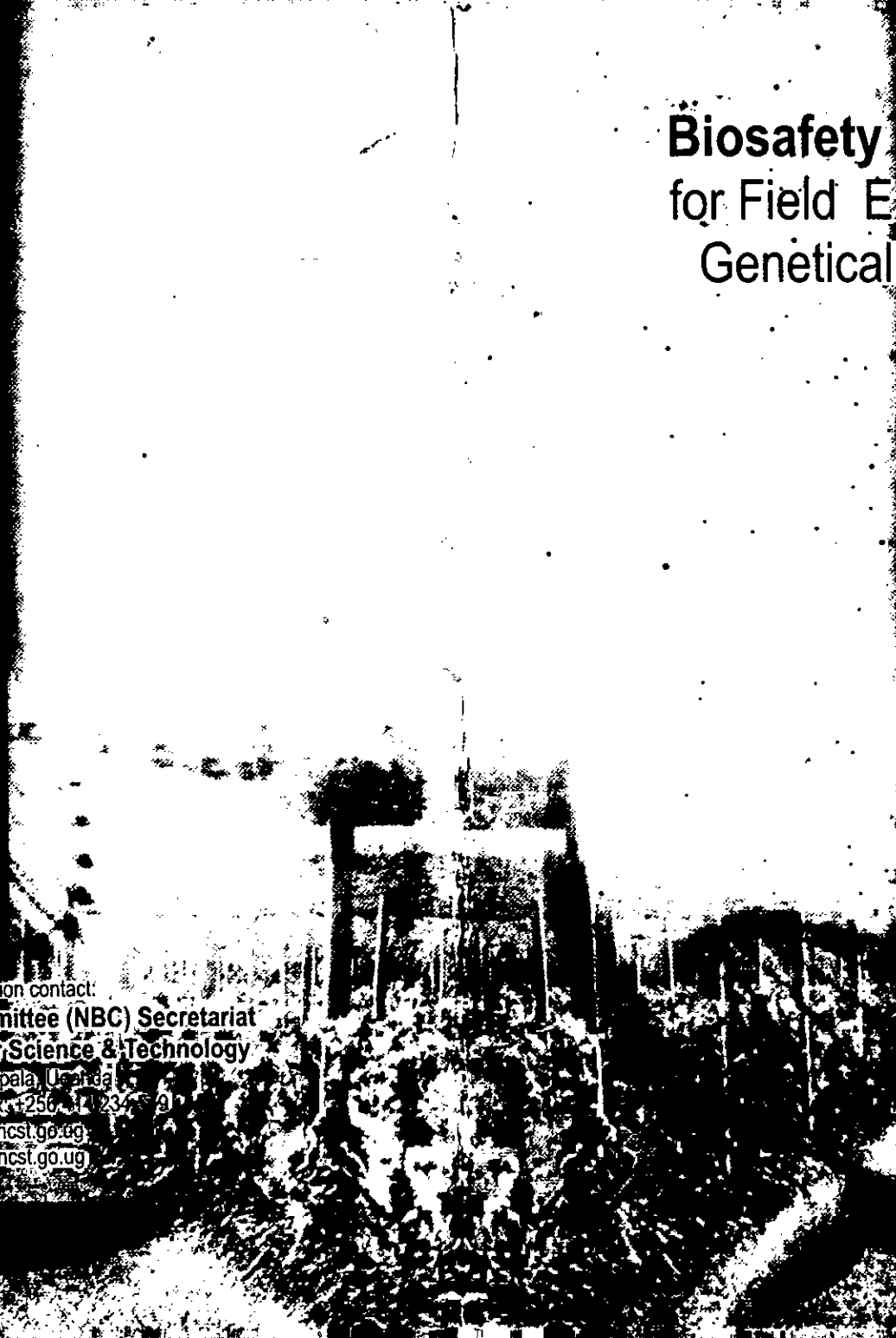
Biosafety Inspection Manual for Field Experiments involving Genetically Engineered Crops



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UNCST

Uganda National [illegible]
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Notes

Biosafety Inspection Manual
for Field Experiments involving Genetically Engineered Crops

Uganda National Council for Science and Technology

Version 1 | August 2007

A publication of the:
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Type of Non-compliance	Advice	Comments
Plants intended not to flower flowering e.g. fro detasseling/de-flowering cases, temporal isolation	Fall-back to isolation distance	When reproductive isolation cannot be established by isolation distance, then the trial should be terminated
Un-authorised trials .	Destruction	Warning letter to Authorised Party, legal action may be taken
INSPECTION OF DISPOSAL, STORAGE AND RECORDS		
Poor Records	Reconcile with trial performance. The record may indicate poor trial management	Warning letter to Authorised Party
Storage of GM material in leaking or non-labelled containers	Recover spilled material, if any, destroy and clean or monitor site for volunteers, if applicable. Initiate appropriate labelling immediately	Warning latter to Authorised Party; Follow-up inspections may be necessary
Spills at disposal site	Recover spilled material, destroy or monitor site for volunteers.	Warning latter to Authorised Party; Follow-up inspections may be necessary
POST-HARVEST INSPECTION		
Prohibited species with in the restricted area	Destroy by roughing or appropriate method	Warning latter to Authorised Party; Follow-up inspections may be necessary
Plants allowed to set seeds	Destroy by roughing or appropriate method. Site subject to extended post harvest	Warning latter to Authorised Party; Follow-up inspections may be necessary

Source: Adapted from KEPHIS Biotechnology and Biosafety Inspection Manual with some changes

Appendix 4:

Examples of Non-compliance and some Advice on how they can be dealt with

Type of Non-compliance	Advice	Comments
INSPECTION OF CONFINEMENT		
Guard row/ Boarder row breakdown	Fall back to isolation distance	When reproductive isolation can not be established by isolation distance, then the trial should be terminated
Insufficient Isolation distance	- Fall beck to other methods of Reproductive isolation - Add the distance and put new permanent markers if circumstances allow and if the crop has not flowered	When reproductive isolation cannot be established by isolation distance, then the trial should be terminated
Prohibited plants within the trial site	Treat them as Genetically Modified Plants, destroy them before flowering	Warning latter to Authorised Party; Follow-up inspections may be necessary
Prohibited plants with in the isolation distance (commercial volunteers or weeds)	Destroy them before anthesis/flowering	Warning latter to Authorised Party; Follow-up inspections may be necessary
Plants allowed to flower and complete anthesis	Advise as appropriate depending on the stage of the growth of the Genetically engineered plants in the trial; may fall back to isolation distance and stringent post-harvest monitoring programme or termination of the trial	Warning latter to Authorised Party; Follow-up inspections may be necessary
Insufficient fencing (damage, delayed setting up of fence)	Advise as appropriate depending on the stage of growth of the GM plants in the trial	Warning latter to Authorised Party; Follow-up inspections may be necessary
Torn bagging material	Fall back to isolation distance, bags replaced immediately	When reproductive isolation cannot be established by isolation distance, then the trial should be terminated
Plants intended to flower not flowering e.g. boarder rows	Fall back to isolation distance	When reproductive isolation cannot be established by isolation distance, then the trial should be terminated

Cont

Preface

Understanding the nature of biological processes has advanced beyond observations, description of natural phenomena, growing of parts of tissues or even cell culture techniques, all of which have depended on chance and gross manipulation. Genetic manipulation techniques of biological processes at molecular level have been enhanced by Recombinant Deoxyribonucleic Acid (rDNA) technology. This has led to deliberate creation of new lines of Genetically Modified (GM) or Engineered (GE) organisms also frequently referred to as Living Modified Organisms (LMOs).

Application of rDNA in crop, animal and human growth and development systems is poised to enhance food production and security, health safety and environmental conservation and biodiversity maintenance. The rDNA technology enhances biological processes which otherwise would have taken place by chance or would be undirected, leading to untimely, unacceptable and undesirable outcomes. However, directed and controlled outcomes of these processes should ensure food security, health safety and technological wellbeing of humanity. In tropical Africa where environmental risk factors have more significant influence in poor plant, animal and human health and production, this (rDNA) technology should be carefully and systematically adopted for laboratory and glass houses (contained) testing, as well as open field but confined trials of crops.

A systematic approach to integrated contained/confined systems requires laboratory and green houses infrastructure as well as small scale areas of restricted access in the open field for Confined Field Trials (CFTs), respectively. A CFT area avoids human and animal interference, enhances reproductive isolation, easy surveillance, removal of volunteers and management of new genetic traits of crops introduced to the geographical area. CFT therefore calls for regulation of the adoption and implementation processes in crop biotechnology, requiring governments' approval, over-seeing the implementation and evaluation processes (development of best, or elimination of poor traits among crops) as well as establishment of effective

control at the local environment through Regulatory Authorities and their inspectors. Regulatory activity requires permanent well trained staff that is well guided using available publicly accessible documents. This has necessitated the production of the Inspection Manual: Procedures for Biosafety Inspection of field experiments with GE crops.

The development of this booklet would not have been possible without the insight of the Uganda Council for Science and Technology's National Biosafety Committee Secretariat and PBS Regional Coordinating Office at IFPRI that provided the lead contacts and organizational points for several workshops, seminars and consultations during the development of this manual.

PBS of IFPRI in Washington, D.C. which through the Donald Danforth Plant Centre in St. Louis, MO. USA, provided the resources. Dr. Mark E. Hasley of PBS ' Donald Danforth Plant Centre gave the leadership to a team of reviewers identified in the acknowledgment section. As the Chairman of the NBC of UNCST, the Regulatory Authority of Biosafety in Uganda, I am privileged to write this preface on behalf of NBC.

You are invited to make the best use of this manual and feel free to notify UNCST on any improvements you may identify, for consideration during future updates.

Professor John Opuda-Asibo

Chairman
National Biosafety Committee - Uganda

Appendix 3:

Post Harvest Land use Restrictions and Monitoring Intervals

Plant Species (GM Crop)	Examples of Appropriate Following Crops	Post-Harvest Period[3] (years)	Monitoring Interval, at least once each (months)
Maize (Zea mays)	Short Stature Dicots (e.g., squash, melon, vegetables)	1	1
Cassava (Manihot esculenta)	Maize or other grain	1	3
Cotton (Gossypium hirsutum)	Maize or other grain	1	1
Banana (*Musa* spp.)	Maize, cotton, short stature dicots	1	3

[3]Period after termination of the trial in which the same or closely related crop species to the one that was being investigated cannot be planted on the same site/plot.

Appendix 2:

Alternative Methods of Reproductive Isolation for some Common Crops

Crop	Method	Requirements
Banana	Bagging and Removal of Male Bud	Bag flower and remove male bud as soon as the distal female bracts curl to expose last formed fingers. Border rows of 3 m (1 row) are required.
Cassava	Border rows	3 m (3 rows) width required. Inspect weekly for integrity and flowering characteristics during the period of flowering of the GM plants.
Cassava	Removal of Flowers	Inspect weekly during flowering period, remove at flower bud stage before flowers open
Cotton	Border rows	12 m width required. Inspect weekly for integrity and flowering characteristics during the period of flowering of the GM plants.
Maize	Bagging of Tassels	Inspect daily during flowering period, bag tassels at emergence prior to pollen shed
Maize	Removal of Male Flowers ('detasseling')	Inspect daily during flowering period, remove tassels before fully emerged, prior to pollen shed.

Foreward

Biotechnology is not a new science as may be perceived by many. It is a science that was applied in bread, beer and wine making three thousand years ago by the utilization of non-pathogenic bacteria. In the crop sector, modern biotechnology encompasses, plant tissue culture, plant genetic modification and molecular breeding. Perceived from the trade point of view in the crop sector, biotechnology has been used to tackle pest, disease and weed problems by the application of recombinant DNA (rDNA) technique, that is, the insertion of a gene or genes in any living organism. Materials generated through the rDNA technique are commonly known as Genetically Modified Organisms (GMOs). Today, biotechnology is applied in several fields including the pharmaceutical and food industries as well as in plant and in animal breeding.

Facing similar trends in the changing world climate like any other country, Uganda is experiencing an upsurge of plant pests and diseases as well as other production constraints. Notably among these are the Banana Bacterial Wilt, cotton bollworm, coffee wilt, cassava mosaic virus, declining soil fertility, the noxious *Striga* weed and these constraints pose a serious threat to the country's agricultural sector of the economy. Unfortunately, limited research and trained personnel do exist for the management of these constraints. Biotechnology, however, has demonstrated the potential for development of methods for management of these production constraints.

Realizing that agriculture contributes the bulk of our foreign exchange through exports mainly to the European Union, Uganda became party to the Cartagena Protocol on Biosafety, that gives guidelines for the trade and trans-boundary movement of GMOs.

The rDNA technique, as opposed to conventional breeding, has been perceived by many as something outside the norm, therefore creating uncertainty among people on the safety of GMOs used as food or feed and their possible effects on the environment. Ethical concerns have also been

raised. This has demanded for strict regulatory measures as coined in the term Biosafety. Such measures are to ensure that no gene escapes into the environment during laboratory work and in experimental confined field trials.

In preparation for Uganda to adopt and safely utilize this technology, several training sessions in Biosafety Inspection particularly in CFT have been conducted within and outside the country in the recent past. The inspection of CFTs in line with the UNCST Act, Cap.209, which empowers UNCST with the responsibility of overseeing new developments in science and technology including biosafety and biotechnology.

This manual therefore presents us with the detailed procedure of how we can inspect the confined field trials of regulated genetically modified crop plants in Uganda. *It should be used in conjunction with the Confined Field Trials Guidelines and the Trial Managers' Handbook that details compliance requirements within the following standard operating procedures (SOPs): SOPs for shipping and storage*, SOPs for confinement, SOPs for Termination of the trial, SOP for post-harvest management, SOPs for reporting and SOPs for incidents.

This document, intended for use by biosafety inspectors is flexible for updating as and when required. It is intended to be used in combination with other relevant documents in Biosafety. The regulation of Confined Field Trials in Uganda can satisfactorily be accomplished by trained inspectors if the content of this document is internalized and adhered to.

It is my wish that this manual is used to ensure that standard operating procedures and CFT guidelines are complied with by those conducting field trials of GM crops.

Dr Peter Ndemere

Executive Secretary
Uganda National Council for Science and Technology

Appendix 1:

Minimum Spatial Isolation Distances for some Common Crops

Plant Species	Minimum Spatial Isolation Distance (m)[2]	Prohibited Plant Species	Monitoring Interval, at least once each (period)
Maize (*Zea mays*)	200	*Zea mays*	1 month
Cassava (*Manihot esculenta*)	100	*Manihot esculenta* Ceara rubber tree (*Manihot glaziovii*)	1 month
Cotton (*Gossypium spp.*)	200	*Gossypium spp.*	1 month
Banana (*Musa spp.*)	Inbreds:.100 Fertile Hybrids: 200	*Ensente, Musa spp.*	Monthly during vegetative growth; bi-weekly after flowering

[2] *Based on Requirements for Breeders' seed*

Appendix Guide

Appendix 1: Minimum Spatial Isolation Distances for some Common Crops

Appendix 2: Alternative Methods of Reproductive Isolation for some Common Crops

Appendix 3: Post Harvest Land use Restrictions and Monitoring Intervals

Appendix 4: Examples of Non-compliance and some Advice on how they can be dealt with

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The Uganda National Council for Science and Technology (UNCST) would like to acknowledge the tireless efforts of the following persons: Ms. Barbara Zawedde - PBS Uganda, Dr. E. Niyibigira - MAAIF, Mr. Arthur Makara - UNCST, Dr. R. Karieyja - MAAIF, and Ms. Grace Akao - MAAIF, for putting together this important document that will be used to ensure safety in the conduct of Confined Field Trials, a critical stage in the evaluation of a genetically modified plant in Uganda. The contributions of Dr. Mark Halsey formerly of Donald Danforth Centre; Lawrence Kent and Katie Moon both from Donald Danforth Centre and Dr. Theresa Sengooba, the coordinator of the Program for Biosafety Systems in East Africa at various stages of development of the document is also greatly appreciated.

UNCST also extends their appreciation to the following: Dr. Roshan Abdallah, Director of Technical services and Head of Biosafety at Tropical Pesticides Research Institute (TPRI) in Tanzania, Dr. Robert Karyeija, Head of Phytosanitary, Uganda Plant Health and Quarantine Department and Ms. Anne Kingiri, Inspector in Charge of Biosafety at Kenya Plant Health Inspectorate Services (KEPHIS) for providing a critical review of this document. All stakeholders that were consulted during the technical review workshop and those that were consulted during the stakeholders' briefing, your input is this manual is acknowledged.

Finally we thank PBS for their support and facilitation without which this document would not have reached this stage. Our sincere apologies go to persons whose inputs into this document may not have been mentioned here, nevertheless, their contributions are all acknowledged.

Inspection Form 9:

Sample Inspection Report for Confirmed Trail or Facility

SAMPLE INSPECTION REPORT FOR CONFINED TRIAL OR FACILITY	
Trial Site:	Location:
Authorisation 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 PA GES 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 Signature:	Date:
Date Submitted:	
Attach copies of relevant Forms where applicable.	

Inspection Form 8:

Review of Trial Records and Exit Interview

REVIEW OF TRIAL RECORDS AND EXIT INTERVIEW WITH TRIAL MANAGER			
Trial Site:		**Location:**	
Authorisation Permit Number:		**Trial Manager:**	
Inspector:		**Date of Inspection:**	
TRIAL RECORDS AND FILES			
Unless otherwise noted, check Yes or No in the appropriate box.		**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:			
Trial Manager Signature:	**Date:**		
Inspector Signature:	**Date:**		

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Acronyms

CFT	Confined Field Trials(s)
GE	Genetic Engineering
GM	Genetic Modification or Genetically Modified
GMO(s)	Genetically modified Organism(s)
IBC	Institutional Biosafety Committee
IFPRI	International Food Policy Research Institute
KEPHIS	Kenya Plant Health Inspectorate Service
LMO(s)	Living Modified Organism(s)
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
NBC	National Biosafety Committee
PBS	Program for Biosafety Systems Project
rDNA	Recombinant Deoxyribonucleic Acid
SOPs	Standard Operating Procedures
TMH	Trial Managers' Handbook
UNCST	Uganda National Council for Science and Technology

Inspection Form 7:

Incidents Resulting from the Confined Trial

INCIDENTS RESULTING FROM THE CONFINED TRIAL		
Trial Site:	**Location:**	
Authorisation Permit Number:	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
INCIDENTS AND INFRACTIONS		
Unless otherwise noted, check Yes or No in the appropriate box.	**YES**	**NO**
Any incidents noted?		
If any serious incidents or compliance infractions have occurred or have been noted, have they been reported to UNCST 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 Signature:	**Date:**	

Inspection Form 6:

Post-harvest Management of Confined Trial Site

POST-HARVEST MANAGEMENT OF CONFINED TRIAL SITE			
Trial Site:	**Location:**		
Authorisation Permit Number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
POST-HARVEST RESTRICTION			
Unless otherwise noted, check Yes or No in the appropriate box.		**YES**	**NO**
What following crop is being grown/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 Signature:	**Date:**		

Glossary

Accidental Release: Discharge of GMO in the environment by mistake, which may exhibit previously unknown pathogenicity.

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

Applicant: A party submitting an application for a confined field trial. Typically, the Applicant is the same as the Authorized Party (see), or is acting in collaboration with the Authorized Party.

Authorized Party: This is the addressee of the Letter of Authorization who is a permanent resident of Uganda, or shall designate an agent who is a permanent resident of Uganda. 'Authorized Party' is construed herein to include any designated agents thereof. The Authorized Party accepts full responsibility for compliance with the Terms and Conditions of Authorization, including all associated legal and financial obligations.

Biosafety Inspector / Inspector: Person designated to check for compliance in safe conduct of trials of Genetically Modified plants

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): 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 material and genes to the trial site.

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'(see).

Construct (n): A segment of DNA to be transferred into a cell or tissue in the process of 'genetic modification' (see).

Devitalisation: A procedure rendering *plants* or *plant products* incapable of germination, growth or further reproduction.

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

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

Genetic Engineering/Genetically Engineered (GE): The genetic modification of organisms by recombinant-DNA techniques. For the purposes of this document, the terms **'genetically engineered (GE)'**, **'transgenic'**, **'genetically modified (GM)'**, **genetically modified organism (GMO)'**, **'living modified organism (LMO)'** and **'regulated'** are equivalent.

Genetic Modification/Genetically Modified (GM): See 'Genetic Engineering'.

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

Letter of Authorization: The letter sent by the NBC to the Authorized Party granting permission for the confined field trial or other activity, including Terms and Conditions of authorization. The Letter of Authorization serves as the legal 'Permit' for the specific trial or activity, according to the Terms and Conditions given therein.

Material Confinement: Measures taken to ensure that GM plant material is not consumed by humans, livestock and animals.

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 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.

Inspection Form 5:

Termination of Confined Field Trial

TERMINATION OF CONFINED FIELD TRIAL			
Trial Site:		**Location:**	
Authorisation Permit Number:		**Trial Manager:**	
Inspector:		**Date of Inspection:**	
TERMINATION OF THE TRIAL			
Unless otherwise noted, check Yes or No in the appropriate box.		**YES**	**NO**
Was NBC 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 UNCST?			
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:			
DEVITALISATION AND DISPOSAL			
Are the measures in place for on-site disposal adequate?			
Describe measures for on-site disposal or devitalisation:			
Comments:			
RECORDS AND REPORTS			
Have all relevant Reports been completed and submitted to NBC?			
Comments:			
Inspector Signature:	**Date:**		

Inspection Form 4:

Technical Instructions for Confined Field Trials

TECHNICAL INSTRUCTIONS FOR CONFINED FIELD TRIAL			
Trial Site:	**Location:**		
Authorisation Permit Number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL DESIGN AND ESTABLISHMENT			
Unless otherwise noted, check Yes or No in the appropriate box.		**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 Technical Instructions?			
Are the plot labels and/or identification 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 sampling required 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:			
Inspector Signature:	**Date:**		

Regulatory Authority: The government body having the statutory authority to regulate an activity. For the testing and introduction of GMOs in Uganda, the Regulatory Authority is vested in UNCST (see), and exercised by the NBC (see).

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.

Technical Instructions: Instructions given by the Authorized Party to trial personnel concerning technical details and requirements of trial conduct. For example, experimental design, plot layout and labelling instructions, observations and sampling requirements are included in the Technical Instructions.

Termination: The end of the experiment in space and time; a conclusion.

Terms and Conditions of Authorization: Specific requirements for biosafety in the conduct of a trial or trials imposed by the NBC at the time of authorization. The Terms and Conditions are attached to the Letter of Authorization sent by UNCST to the Authorized Party.

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

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

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

Section Guide

Section 1: Introduction

Section 2: Objectives

Section 3: Preparing for Inspection

Section 4: The Process of Inspection

Section 5: Critical Aspects of Inspection

Section 6: Checklists for Typical Inspection Requirements

Inspection Form 3:

Confinement of Field Trials with GM Plants

CONFINEMENT OF FIELD TRIALS WITH GM PLANTS			
Trial Site:	**Location:**		
Authorisation Permit Number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL ESTABLISHMENT			
Unless otherwise noted, check Yes or No in the appropriate box.		**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 UNCST within five (5) days after planting?			
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 and 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 Signature:	**Date:**		

Inspection Form 2:

Shipping and Storage of GM Plant Materials

SHIPPING AND STORAGE OF GM PLANT MATERIAL[1]			
Trial Site:	Location:		
Authorisation Permit Number:	Trial Manager:		
Inspector:	Date of Inspection:		
PACKAGING AND LABELLING			
Unless otherwise noted, check Yes or No in the appropriate box.		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 disposed of?			
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:		

[1]GM material is not exempted from seed and plant Phytosanitary import requirements

Section 1: Introduction

When plants have traits introduced by modern genetic techniques such as recombinant DNA (rDNA) technologies, they are called 'genetically modified' (GM), genetically engineered' (GE), or 'living modified organisms' (LMOs). The testing of these types of plants is regulated by government agencies, which oversee their evaluation and must give their approval on a case-by-case basis before a new GM variety may be placed on the market in a general or unrestricted release. Because the government regulates GM plants, research on experimental lines or varieties prior to their approval for release is done under controlled conditions, either in a laboratory or glasshouse ('contained' testing), or in a restricted area outdoors, which is called a 'confined field trial' (CFT).

This Manual is intended as a resource material for use by Biosafety Inspectors designated by UNCST to inspect or oversee confined field trials or facilities for compliance with the Confined Field Trial (CFT) guidelines.

In Uganda, biosafety in the conduct of confined field trials is ensured by adherence to the requirements found in several types of documents:

- CFT Guidelines, which gives the general conditions required for the safe conduct and reporting of confined field trials.
- Trial Managers' Handbook (TMH) which contains the following Standard Operating Procedures (SOPs):
  - Data Quality and Integrity [section 2.0 of TMH)
  - Shipment and Storage (sect. 3.0 of TMH)
  - Confinement (sect. 4.0 of TMH)
  - Sampling (sect. 5.0 of the TMH)
  - Termination (sect. 6.0 of the TMH)
  - Post-Harvest Management (sect.7.0 of the TMH)
  - Incidents and Contingency Planning (sect. 8.0 of the TMH)
  - Reporting (sect. 9.0 of the TMH)
- Terms and Conditions of Authorization for conduct of a specific trial, issued by the UNCST upon approval of a specific trial.

- Technical Instructions for conduct of a specific trial, provided by the Authorized Party to trial personnel.
- Guidance Documents, which provide instructions from UNCST on management of GM testing for Applicants and Authorized Parties.
- This Inspector's Manual, which provides instructions for Biosafety Inspectors of confined trials.

To be effective, individuals inspecting CFTs must be familiar with all of these documents, in order to fully comprehend and discharge their duties. It is especially critical that Inspectors have complete command of the requirements found in the Terms and Conditions of Authorization issued by the UNCST for a specific trial, and the SOPs which provide guidance for trial conduct. The requirements found in these documents are the foundation for biosafety in the conduct of confined field trials, and forms the basis of the inspection procedures outlined in this Manual.

It should be well-noted by Biosafety 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 procedures as relevant to those trials or activities which they have oversight responsibility.

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

i. preventing the escape from the trial site of novel genes in pollen, seed or other plant parts;
ii. preventing GM plant material from being consumed by humans and/or animals; and
Iii. preventing GM plants from escaping from confinement and establishing and persisting in the environment.

With the achievement of these three goals, novel genes and their products may be confined to the field trial site, and their release into the general environment prevented.

Inspection Form 1:

Facility and Records Inspection Form

FACILITY AND RECORDS INSPECTION		
Trial Site/Facility:	**Location:**	
Authorisation Permit Number:	**Trial Site/Facility Manager:**	
Inspector:	**Date of Inspection:**	
FACILITY		
Unless otherwise noted, check Yes or No in the appropriate box.	**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 that GM and non-GM materials can 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 the 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 below. 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?		
Is the site properly labelled?		
Other (describe):		
Comments:		
Inspector Signature:	**Date:**	

As noted in CFT Guidelines, 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 only limited to the fulfilment of these procedures in achieving the goals of confinement outlined above; they are also required to take all reasonable steps to achieve these goals.

Biosafety is one of the goals of UNCST, 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 Uganda and its citizens.

Inspection Forms Guide

Inspection Form 1:	Facility and Records Inspection Form
Inspection Form 2:	Shipping and Storage of GM Plant Materials
Inspection Form 3:	Confinement of Field Trials with GM Plants
Inspection Form 4:	Technical Instructions for Confined Field Trials
Inspection Form 5:	Termination of Confined Field Trial
Inspection Form 6:	Post-harvest Management of Confined Trial Site
Inspection Form 7:	Incidents Resulting from the Confined Trial
Inspection Form 8:	Review of Trial Records and Exit Interview
Inspection Form 9:	Sample Inspection Report for Confirmed Trail or Facility

Section 2: Objective

The main objective of this manual is to provide instruction and guidance to Inspectors of confined field trials. Inspection and oversight for confined trials serve several purposes:

- A field trial inspection is the only certain means of assessing a trial and verifying compliance with the Terms and Conditions of Authorization and other requirements of a specific trial.
- Inspection is needed to determine if facilities used for storage of GM plant material comply with relevant requirements.
- Inspection of trial documents ensures that the requirements of data quality and integrity are met.
- The Inspector may use the opportunity to increase awareness of trial requirements with the Trial Manager and Authorized Party, thus helping to ensure continuing biosafety.
- The Inspector is available to the Trial Manager and Authorized Party to answer questions and provide clarification of any requirements.
- The process of inspection improves the knowledge and skill of the Trial Manager and Authorized Party in fulfilling the requirements of the trial. This helps foster self-compliance, and advances the goal of continued and safe testing of GM crops.

This Manual provides a basis for a logical and step-wise approach to preparing for the inspection, conducting the inspection of the field site and documentation, interviewing field personnel for pertinent information, obtaining necessary confirmation of key information, writing the inspection report, notifying UNCST 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 Forms & Appendices

6.4.6 *Post-Harvest Requirements*

Progeny arising from the GM plants at the field trial site are known as 'volunteers', and must be prevented from establishing and flowering after termination of the trial. Depending on the nature of the propagative material remaining in the trial site and the biology of the crop plant, a post-harvest period will be defined. Details of post-harvest management may be found in the SOP for Post-harvest Management in the TMH (also see Appendix 3).

6.4.7 *Contingency Planning*

The Authorized Party will establish a contingency plan for actions to be taken in case of emergency, or of unauthorized or accidental release of GM material. Details may be found in the SOP for Incidents.

NOTE: *Specific Terms and Conditions of trial are issued by the NBC to the Applicant in the decision document and these vary depending on the nature of the crop and the investigations to be conducted on the crop in the trial. The Inspector must have a copy of terms and conditions of each trail they are to inspect.*

Section 3: Preparing for Inspection

Timing of inspections is typically based on crop growth stage, progress or status of the trial, or upon specific request from NBC. Critical points at which an inspection may be targeted are at site preparation, 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 Inspectors will also verify compliance with specific Technical Instructions provided by the Authorized Party to trial personnel. Phytosanitary inspections are also conducted when required. 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 by having 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:

1. A copy of the Letter of Authorization, including the specific Terms and Conditions of the trial;
2. Import documents to show the nature and origin of the plant material;
3. Site location map;
4. Contact details of the Trial Manager and/or Authorized Party;
5. Copies of the SOP booklet 'Conducting a Confined Field Trial';
6. A copy of this Manual and Inspection Checklists, a clipboard, notepaper and pens;
7. A copy of the Technical Instructions for the trial to be inspected;

8. Any additional technical information that may be needed, for example, relevant crop growth stages, a list of approved pesticides for use in the crop, etc;
9. Previous inspection reports for the site to be inspected were appropriated.

The Inspector typically arranges in advance a mutually agreed upon time for the visit with the Trial Manager, except where an unannounced inspection is to be done. When inspections are scheduled in advance, the Authorized Party should also be notified of the upcoming visit. The responsible IBC may be informed, if appropriate. Unannounced inspections may be carried out at any time at the discretion of UNCST, without prior notification of the Authorized Party or Trial Manager. Inspections may be carried out at any time during working hours. The Trial Manager must provide access to the trial site or storage area, and must make records available for the purpose of inspection by Biosafety Inspectors.

In addition to the documents required for any site visit, certain equipment may also be helpful or required, depending on the circumstances:

- A Global Positioning System (GPS) unit
- A camera
- A Timing Device
- A measuring tape or measured rope appropriate to verify isolation distances
- Inspector's credentials (if not personally known to the Trial Manager)
- Transport to/from the site
- Note book

them from being inadvertently mixed with non-GM material. Detailed requirements may be found in the SOP for Shipping and Storage in the TMH.

6.4.3 Reproductive Isolation

To prevent the escape of genes from the trial site, GM plants being tested shall be reproductively isolated from sexually compatible plant species in proximity to the trial site.

The primary means of achieving reproductive isolation is by use of a spatial isolation distance between plants in the trial site and any plants with which the GM plants are sexually compatible, which are designated as 'prohibited plants'. Minimum spatial isolation distances vary depending on the reproductive biology of the plant species. Guidance for specific crops and circumstances will be availed by UNCST. Examples of few crops are given in Appendix 1.

Alternative methods of reproductive isolation may be used in place of or in addition to spatial isolation distance, depending on the crop plant and the circumstances of the specific trial. Examples of alternative methods may be found in the SOP for Confinement in the TMH (also see Appendix 2).

6.4.4 Field Site Maintenance and Monitoring

The trial site will be maintained and monitored during the course of the trial in order to restrict gene flow and loss of GM material from the site. Details may be found in the SOP for Confinement in the TMH (also see Appendix 1).

6.4.5 Harvest and Disposal of GM Plant Material

No plant material from a confined field trial site may be used as human food and/or animal feed. Plant material harvested from a confined trial that is not retained for future research work shall be disposed of according to the requirements of the SOP for Disposal in the TMH.

verified as a condition of trial authorization. Trial managers and technical personnel shall provide evidence of education, training or experience in the safe handling of genetically modified organisms. An Application for a confined field trial will be rejected if there are reasonable grounds to believe that the Applicant does not have sufficient resources or personnel to comply with the Terms and Conditions of authorization.

6.4 Procedures for Confined Field Trials

6.4.1 Establishment of procedures

Procedures for the conduct of confined field trials are intended to accomplish three important goals: *1) preventing the escape from the trial site of novel genes in pollen, seed or other plant parts, 2) preventing GM plant material from being consumed by humans and/or animals, and 3) preventing GM plants from escaping from confinement, establishing and persisting in the environment.* With the achievement of these three goals, novel genes and their products may be confined to the field trial site, and their release into the general environment prevented. In order to establish effective procedures to achieve these goals, Authorized Parties are required to follow Standard Operating Procedures (SOPs) for the safe transport and storage of GM plant material, for reproductive isolation and material confinement of the GM plants on the field trial site, for disposal of plant material and volunteers at the trial site, and for contingency planning. SOPs addressing the requirements in detail for specific crop plants are given detail in the TMH and shall also be posted on the UNCST website **www.uncst.go.ug** for ease of accessibility. These SOPs include those in the sections following.

6.4.2 Shipping and storage

GM plants or plant parts must be shipped and stored in a fashion that clearly identifies them as GM material, that prevents their unintended release into the environment, and that prevents

Section 4: Process of Inspection

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

1. The Inspector prepares him/herself for the Inspection by becoming familiar with the biosafety requirements and technical aspects of the trial.
2. The government Agency in charge of inspections shall arrange the visit with the Trial Manager and assign a specific Biosafety Inspector to visit the trial site for inspection. If the Inspector has any questions concerning the SOPs, the specific Terms and Conditions of the trial, or on any technical aspects of the crop, trait or trial, these questions should be clarified before the site visit.
3. 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.
4. The Inspector conducts a visual examination of the site, facility or processes being inspected, and takes careful note of compliance with requirements, using the checklists or notes.
5. The Inspector reviews documents and files, noting adherence to trial requirements and SOPs.
6. The Inspector interviews the Trial Manager or other trial personnel as well as people living close to the trial site, if needed, so as to address any questions or points of clarification. *Note that steps 3, 4, 5 and 6 may be completed in any order, and each may be repeated as needed.*
7. The Inspector completes a draft of the checklists, noting any concerns or issues.
8. 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 on any upcoming compliance requirements.

9. In the case of significant findings of non-compliance, the Inspector shall inform the Trial Manager, Authorized Party and NBC Secretariat immediately, preferably while still at the site and prepare a written communication and submit it in 24 hours. NBC Secretariat shall determine an appropriate course of action and communicate requirements to the Trial Manager, Authorized party and/or any other responsible persons.

10. The Inspector completes a report on the inspection and forwards it to NBC Secretariat at UNCST within five working days after returning to his/her workplace. Reports shall be made in duplicate; one to be sent to the NBC Secretariat (address in section 5.10), the other to be retained by the inspector.

11. All notes, checklists and copies submitted reports shall be maintained by the Inspector in secure storage.

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

Section 6:

General Terms and Conditions For Confined Field Trials

6.1 Responsibility of the Authorized Party

It is the responsibility of the Authorized Party to ensure compliance with the Terms and Conditions of authorization. This responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of establishing and maintaining the trial site or handling the genetically modified plant material. Compliance infractions include unauthorized or accidental release, entry of GM plant material into human or animal food while still under test or gross negligence of stated Terms and Conditions. Substantial fines may be imposed by UNCST for instances of non-compliance.

6.2 Size and Number of Confined Field Trials

In order to maintain the integrity of the review and approval system, and to ensure adherence to the requirements described herein, UNCST may restrict the number of confined field trial applications or approvals granted, and/or the size of authorized trials. These restrictions shall be determined by specific circumstances, and may be applied with respect to Applicants, genetic constructs, phenotypic traits, field sites or other criteria at the discretion of UNCST. Applicants should consult with the NBC Secretariat for information on any restrictions that may be in force, prior to submitting an Application.

6.3 Trial Resources and Personnel

The Authorized Party is required to have the physical and personnel resources sufficient to comply with all Terms and Conditions of authorization. Proposed trial sites shall be inspected and their adequacy

Section 5: Critical Aspects of Inspection

5.1. Facilitation of Inspectors

UNCST shall facilitate its staff or any other contracted parties that shall be conducting biosafety inspections.

5.2 Inspection of Facility and Records at the Trial Site | (Form 1)

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; adequacy of the proposed trial site; and adequacy of disposal method. Inspectors shall conduct an examination of the facility and records, taking note of specific requirements in the above areas.

5.3 Shipping of GM Plants and Plant Products | (Form 2)

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.

Inspectors shall conduct an examination of the facility and documents in accordance with the Shipping and Storage SOP (sect. 2.0 of the TMH), taking note of the following:

- Packaging and labeling;
- Shipping documentation;
- Storage area for GM material.
- Disposal of package and extra GM material.

5.9 Data Quality and Integrity of Trial Records | (Form 8)

Data quality and integrity standards are intended to ensure that all documentation associated with the trial is clear, authentic, and available to trial personnel. Data quality is essential to validation of both confinement measures and technical methodology used in the trial. Inspectors shall conduct an examination of the trial files and documentation, taking note of its adequacy and compliance the requirements as provided for in the SOP for Data Quality and Integrity (sect. 2.0 of the TMH).

5.10 Exit Interview

An exit interview with the Trial Manager is critical to on-going learning, understanding and communication about the confined field trials. 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.

5.11 Inspection Report | (Form 9)

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. The Inspection Report shall be submitted to NBC within 3 working days after the Inspector has returned to his/her workplace. The report shall be submitted to:

National Biosafety Committee Secretariat
Uganda National Council for Science and Technology
P.O. Box 6884, Kampala, Uganda
Telephone: +256 414 250499 or 705 500
Facsimile: +256 414 234579
Email: uncst@uncst.go.ug
Website: http://www.uncst.go.ug

5.4 Confinement of Field Trials with GM Plants | (Form 3)

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

Inspectors shall conduct an examination of the trial site and documents in accordance with the Confinement SOP (sect. 4.0 of the TMH), taking note of the following:

- Site security and trial establishment;
- Measures for reproductive isolation;
- Monitoring, documentation and reporting requirements.

5.5 Technical Instructions from the Authorized Party | (Form 4)

Technical instructions for a confined field trial typically include details that are not directly related to biosafety, but rather to the 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 NBC and biosafety inspectors. 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.

5.6 Termination of Confined Field Trial | (Form 5)

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

Inspectors shall conduct an examination of the trial site and documents in accordance with the Termination SOP (sect. 6.0 of the TMH), taking note of the following:

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

5.7 Post-Harvest Management of the Trial Site | (Form 6)

The critical aspects of post-harvest management of a confined trial are: maintaining security and control over the field 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.

Inspectors shall conduct an examination of the trial site and documents in accordance with the Post-Harvest Management SOP (sect. 7.0 of the TMH), taking note of the following:

- Post-harvest restriction requirements;
- Post-harvest monitoring and documentation requirements.

5.8 Incidents Affecting the Trial | (Form7)

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 may be required by NBC, which will provide specific requirements for such inspection, according to the characteristics of the incident. Guidance of handling of incidents is provided in the SOP for Incidents (sect. 8.0 of the TMH).