A Practical Manual for Safe Conduct of Confined Field Trials

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PREFACE

Confined field trials are essential to the scientific and economic as well as political and social success of any biosafety system, and are a necessary prerequisite to the unconfined (general) environmental release of transgenic plants. Confined field trials serve multiple purposes. For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel plant-trait combinations in the open environment. In this regard, confined field trials serve the same purpose as conventional breeders' trials.

Within the product development pathway, confined field trials represent the first controlled introduction into the environment of genetically modified plants. As such, they represent a distinct activity from work performed in contained facilities, such as laboratories, greenhouses and screen houses, and from unconfined or commercial release to farmers. At the point of confined field trial, the potential environmental risks of a particular transgenic plant may not be fully understood and this poses special challenges to regulatory oversight and environmental risk management.

This Guide is intended as a simple and convenient reference on appropriate biosafety and confinement levels for GMO research conducted in confined fields. The safe conduct of confined field trials can only be accomplished through the combination of a robust regulatory framework, science-based risk mitigation measures, trained and vigilant inspection staff, and trained field personnel dedicated to abiding by the terms and conditions of trial authorization. As evidenced by some experiences in both developing and industrialized countries, weaknesses in any of these areas become quickly apparent, usually to the determent of public trust. Public opinion research has demonstrated that public acceptance of new technologies, including modern biotechnology, is largely dependent on confidence in regulatory structures and process. Even more generally, trust in the integrity and institutional governance of regulatory bodies is essential to securing market access both at home and abroad.

The Guide also provides instructions and guidelines for all aspects of biosafety for confined field trials in Tanzania in form of standard Operating Procedures (SOPs). The SOPs give detailed instructions for shipping and storage, establishment, maintenance and confinement of confined field trials; termination and post-harvest management of the trial site; and reporting of results to National Biosafety Focal Point (NBFP). The forms provided are intended as example formats for collecting typical information required for documentation of compliance requirements. These forms may be customized in the Terms and Conditions of authorization for a particular trial. Similarly, the formats suggested for reporting of results may also be modified if needed to meet specific requirements set forth by the NBFP for a particular trial.

Procedures provided here are for the use of all Trial Managers, Technical personnel, agents of the Authorized Party, and government officials engaged in planning, conducting or overseeing confined field trials of GM plants in Tanzania. This manual is intended as guidance and should not be considered as the only authoritative source. Readers are encouraged to seek additional guidance from the NBFP and other regulatory bodies.

ACKNOWLEDGEMENT

The successful preparation of this Manual is a result of joint efforts of several experts and institutions that deserve a vote of appreciation. Due to space limitation, we cannot mention all of them. However, we assure them of our heartfelt appreciation and that we value their cooperation and support.

We are deeply indebted to the team of experts that compiled and edited this Manual for their commendable efforts and inputs. The team comprised Dr. S. R. Mwinjaka, Dr. C.M. Shayo, Mr. F. Ngerageza, Mr. S. Nkondokaya, Mr. O. Kamukuru, and Mr. T. Bwana from the Vice President's Office; Dr. A. Kullaya and Dr. E. Mneney from Mikocheni Agricultural Research Institute (MARI); and Dr. Roshan Abdallah from Tropical Pesticides Research Institute (TPRI).

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Ruth H. Mollel
Permanent Secretary
VICE PRESIDENT'S OFFICE

CONTENTS

ABBREVIATIONS AND ACRONYMS

BL	Biosafety Level
CFT	Confined Field Trial
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
GMP	Genetically modified Plant
GMO	Genetically Modified Organism
HEPA	High Efficiency Particulate Air
HV	Host-Vector
IBC	Institutional Biosafety Committee
MARI	Mikocheni Agricultural Research Institute
NBAC	National Biotechnology Advisory Committee
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBFP	National Biosafety Focal Point
SOP	Standard Operating Procedures (SOPs).
rDNA	recombinant Deoxy ribonucleic acid
UNEP	United Nations Environment Program
VPO	Vice President’s Office

DEFINITION OF TERMS

Accidental Release	Any unauthorized release of GMOs in the environment; human food and/or livestock feed chains.
Applicant	A party submitting an application for a confined field trial. Typically, the Applicant shall be a permanent resident of the United Republic of Tanzania or in the case of a non-resident shall designate an agent who is a permanent resident of the United Republic of Tanzania. In the case of a corporation, permanent resident means a company incorporated in Tanzania, and in the case of a natural person, permanent resident means a citizen of the United Republic of Tanzania, either by birth or acquisition. The applicant need not to be the owner of the GMO, in which case a signed statement is required from the owner authorizing representation by the applicant. All correspondence with respect to the application for confined field trial, including the notification of authorization, will be addressed to the applicant.
Application	An application is the data package submitted for each genetically engineered plant species intended for use in a confined field trial. An application should cover only one transgenic event.
Authorized Party	The addressee of the letter of Authorization. The Authorized Party accepts full responsibility for compliance with the Terms and conditions of authorization, including all associated legal and financial obligation
Biohazard	Potential danger posed by a living or biologically-derived material.
Biosafety	is a term used to describe efforts used to ensure that the use for of GMOs or its products would pose an unacceptable risk to human and animal health or the environment.
Biotechnology	Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
Compliance Infraction	Violation of the Terms and conditions of Authorization.

Confined Field Trial	A confined field trial (CFT) is a restricted environmental release of a genetically engineered plant, for research purposes, under terms and conditions intended to mitigate the establishment and spread, in the environment, of seed or of genetic material from plants derived from the seed, and the interaction of the seed or genetic material with the environment. A single confined field trial may comprise one, or more, transgenic events of a single plant species that are subject to the same terms and conditions of confinement. These terms and conditions include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. The requirements of this guideline, including the terms and conditions of a confined field trial, do not apply to material that has received prior authorization for unconfined release within Tanzania.
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	A segment of DNA to be transferred into a cell or tissue and type using a specific genetic modification
Compliance	Fulfilling the requirements of the Terms and conditions of Authorization, especially with regard to confinement measures.
Compliance Document Binder (CDB)	Is a file prepared to keep all records used to document all steps of a confined field trial such as transport, storage, current season inspection, harvest and disposition, and post harvest monitoring of Genetically modified (GM) plants and plant products.
Contained use	Any operation, undertaken within a facility, installation or other physical structure, which involves GMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment**.**
Containment	Act of restricting or preventing the spread, leak or escape of an experimental object**.**

Event	A transformation event refers to each individual transgenic line produced from the modification of a single plant species using a specific genetic construct. For example, two lines of the same plant species transformed with the same or different constructs constitute two events.
Genetically modified (GM) Plants and Plant Products	Are plants and plant products developed through genetic medication of organisms by recombinant DNA techniques.
Genetically Modified Organism (GMO)	Any organism which has been altered or produced through genetic engineering, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering. For the purpose of this guideline the terms genetically modified plants, genetic engineered plants and transgenic plants should be used interchangeably.
Incident	Any occurrence that causes, or threatens to cause, a breach of confinement of GM plant material
Living organism	Any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.
Permit	A written document issued by the appropriate authority for the introduction of GMOs under conditions that will avoid or minimize associated risks to human and animal health and the environment.
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.
Receiver	A person who has been appointed by the Authorized party to receive the GMOs for storing in the storage facility.
Regulatory Authority	An institution that has a legal mandate to enforce biosafety legal instruments such as legislation, regulations and guidelines
Reproductive Isolation	Measures taken to prevent, principally, pollen-mediated gene flow from plant 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
Trial Manager	The individual 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
Shipper	An agent, company or a person that transports GMOs between research facilities, storage facilities, quarantine station, and field trial sites in Tanzania.
Vector or vector agent	Organisms or objects used to transfer genetic material from the donor organism to the recipient organism.
Volunteers	progeny arising from the GM crop in a confined field trial site.

LIST OF FIGURES

LIST OF TABLES

1.0 INTRODUCTION

The use of biotechnology to modify plants has become a common practice in agricultural and horticultural research. Unlike ordinary research materials used in laboratory, greenhouse and field studies, transgenic organisms are subject to special rules intended to ensure that they are used in a way that does not pose an unacceptable risk to human and animal health or the environment.

Within the product development pathway, confined field trials represent the first controlled introduction into the environment of genetically modified plants. As such, they represent a distinct activity from work performed in contained facilities, such as laboratories, greenhouses and screen houses, and from unconfined or commercial release to farmers. At the point of confined field trial, the potential environmental risks of a particular transgenic plant may not be fully understood and this poses special challenges to regulatory oversight and environmental risk management.

This Manual is intended as a simple and convenient reference on appropriate biosafety and confinement levels for GMO research conducted in confined fields. The safe conduct of confined field trials can only be accomplished through the combination of a robust regulatory framework, science-based risk mitigation measures, trained and vigilant inspection staff, and trained field personnel dedicated to abiding by the terms and conditions of trial authorization. As evidenced by some experiences in both developing and industrialized countries, weaknesses in any of these areas become quickly apparent, usually to the determent of public trust. Public opinion research has demonstrated that public acceptance of new technologies, including biotechnology, is largely dependent on confidence in regulatory structures and process. Even more generally, trust in the integrity and institutional governance of regulatory bodies is essential to securing market access both at home and abroad. Likewise, the poor performance of some groups conducting confined field trials calls into question not only their own reputation, but also tarnishes the image of the entire development community and the technology.

1.1 Definition of Confined Field Trial

A confined filed trial is a small-scale experimental field trial of a genetically modified plant species carried out to collect the data necessary for a complete environmental risk assessment that is performed under terms and conditions that mitigate impacts on the surrounding environment.

Embodied in this definition are three important considerations. Firstly, it is a small-scale activity, usually about one hectare (ha). Secondly, a confined trial is an experimental activity conducted to collect data, either on agronomic performance or on potential biosafety impacts. It is usually the case that collection of such field trial data is a prerequisite to completing the environmental risk assessment. And finally, the trial is conducted under conditions known to prevent the pollen-or seed-mediated dissemination of new genes into and within the environment, to prevent the persistence

in the environment of the transgenic plant or its progeny, and to prevent the introduction of the transgenic plant or plant products into the human food or livestock feed pathways.

1.2 Purpose of Confined Field Trials

Confined field trials are essential to the scientific and economic as well as political and social success of any biosafety system, and are a necessary prerequisite to the unconfined (general) environmental release of transgenic plants. Confined field trials serve multiple purposes. For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel plant-trait combinations in the open environment. In this regard, confined field trials serve the same purpose as conventional breeders' trials.

Confined field trials are also necessary to collect the agronomic and ecological data required to complete the environmental safety assessment of the transgenic plant. As part of the core characterization of a transgenic plant, it is necessary to measure the levels of protein expression from any newly introduced genes, both in a range of plant tissue and over the course of plant development.. These measurements are generally performed on field-grown plants and are used to predict levels of exposure to novel dietary proteins for humans or livestock animals consuming the edible portions of the transgenic plant or derived plant products. In addition, confined field trials permit the production of sufficient quantities of plant material for use in livestock feeding trials and to conduct compositional analyses, which are necessary for human food safety assessment.

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, and
c) 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.

In order to meet the above goals, it is mandatory for 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.

1.3 Scope

This Handbook provides general instructions and guidelines for all aspects of biosafety for confined field trials in Tanzania in form of Standard Operating Procedures (SOPs). The SOPs give detailed instructions for shipping and storage, establishment, maintenance and confinement of confined field trials; termination and post-harvest

management of the trial site; and reporting of results to NBFP. The forms provided are intended as example formats for collecting typical information required for documentation of compliance requirements. These forms may be customized in the Terms and Conditions of authorization for a particular trial. Similarly, the formats suggested for reporting of results may also be modified if needed to meet specific requirements set forth by the NBFP for a particular trial.

The procedures provided here are for the use of all Trial Managers, Technical personnel, agents of the Authorized Party, and government officials engaged in planning, conducting or overseeing confined field trials of GM plants in Tanzania.

This manual is intended as guidance and should not be considered as the only authoritative source. Readers are encouraged to seek additional guidance from the NBFP and other regulatory bodies.

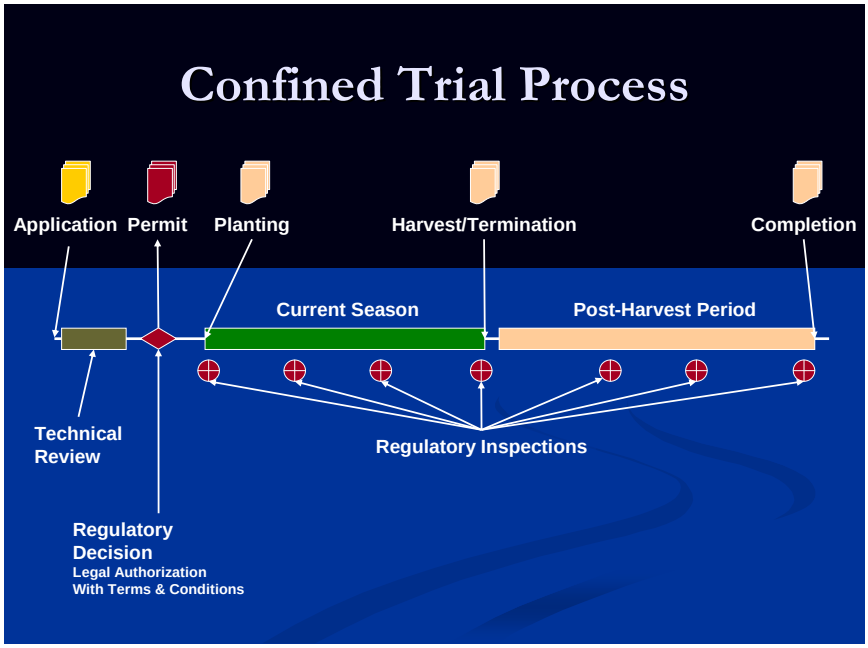

Figure 1: Confined Trial Process – Application to completion

1.4 Legal Authority

The Environmental Management Act (2004), administered by the Ministry responsible for Environment, provides authority to regulate the importation, development, handling and use of genetically modified organisms and their products.

1.5 Application for confined field trials

The application form (Annex I) must be completed and submitted by regular mail or courier delivery to:

Permanent Secretary
Vice President's Office
P.O. Box 5380 Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

If the genetically engineered plant, or plant product, intended for use in a confined field trial is to be imported, then an Import Permit must be obtained from the relevant regulatory authorities.

1.5.1 When to apply

Applications for confined field trials must be received at least 180 days in advance of the proposed release date. Applications that are judged to be incomplete or deficient are returned to the applicant with a request to submit a supplementary application that addresses any deficiencies. Supplementary applications are handled in the same manner as original applications.

1.5.2 Review and approval process

The application will be reviewed by regulatory authorities and competent authorities. Following the completed review, authorization of the confined field trial will be granted or denied. Where authorization is denied, the applicant is informed of the reason(s).

1.5.3 Review and approval process

Renewals of authorization for confined field trials, including ongoing trials of perennial genetically engineered plants, may be granted for trials that are identical (i.e. same species, construct and location) to those approved in previous years.
Gene constructs, genetic modifications, plant material, trial purposes, experimental protocols, and the trial sites (including size and location) must be identical to those reviewed and authorized in previous years. The review of an application for renewal of a confined field trial will include a consideration of compliance history, inspection reports and previous year's technical report.

The terms and conditions of authorization required in previous years still apply, however, the Minister reserves the right to modify, add, or remove any condition of authorization upon renewal

1.5.4 Review and approval process

For applications for a new confined field trial, or a renewal, use the application form included in Annex 1 of this manual. The application form, including any enclosures, must be printed only on one side and additional material must be organized and numbered to correspond to the appropriate Part and sub-Part. of authorization for confined field trials, including ongoing trials of perennial genetically engineered plants, may be granted for trials that are identical (i.e. same species, construct and location) to those approved in previous years.

When the intention is to test plants derived from more than a single genetic construct, for example, in the case of insect-resistant transgenic events of the same plant species with the same phenotype (e.g., resistance to cotton bollworm) produced by transformation with two different vector constructs (e.g., different cry genes), two separate applications must be submitted.

1.5.5 Review and approval process

In situations where completion of the application would entail the disclosure of confidential business information (CBI) or trade secrets, a CBI and a CBI-deleted application must be submitted. For information claimed as CBI, the applicant must provide a written justification. Published literature usually cannot be claimed as CBI. Applicants should bear in mind that NBFP may provide copies of the non-CBI application to outside experts for review, and if insufficient information is present in the non-CBI copy, it may hinder the provision of comments or concurrence with NBFP's initial review.

1.5.6 Fees

The application fee is US$ xxx for each application and US$ xxx for processing of the renewal application .The review and processing of an application will only commence once payment of an application fee has been received by NBFP. Once review of an application has been initiated, the application fee will not be refunded.

2.0 STANDARD OPERATING PROCEDURES

2.1 Standard operating procedures for shipping

The requirements in this section apply to the transport of GMOs between research facilities, storage facilities, quarantine stations and field trial sites.
The Shipper shall inform the Receiver and the Regulatory Authority of the date of shipment and the expected date of the arrival of the consignment. This information shall also be kept in the Compliance Document Binder.

2.1.1 Packaging

All GM plant materials for shipping or transport must be packaged in such a fashion to prevent any accidental release. Packaging shall also ensure that tampering can be detected easily.

a) GMOs shall be secured within a primary container.

b) Each sealed, primary container shall contain only GMO of a single type derived from one line of a single submission.

c) The primary container shall be a plastic bag of no less than 5 mm thickness or a sealed envelope or package constructed of a tear and moisture resistant material.

d) The primary container shall be placed within a sealed, leak-proof, secondary container that shall be contained within a sealed, leak-proof tertiary container.

e) The secondary container may contain multiple labeled primary containers.

f) The secondary container shall be resistant to breakage or water damage and shall be constructed of materials such as corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

g) The tertiary container shall be resistant to breakage or water damage and shall be constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

h) Primary, secondary and tertiary containers used to transport GMOs shall be sanitized prior to filling and after the plant material has been removed. Alternatively, containers may be destroyed by autoclaving, incinerating or burning.

i) If large-sized materials are to be transported as the result of a confined field trial, guidance should be sought from NBFP/NBC on specific packaging requirements appropriate to the material proposed to be transported. For small –sized materials, packaging shall be done as described above.

Figure 2: Primary, secondary and tertiary containers used to packaging GMOs

2.1.2 Labeling

a) Primary containers shall be labeled with the event name of the material contained within, and with the Shipment Number found on the Record of Transport.

b) The original Record of Transport shall be placed within the secondary container.

c) All tertiary containers used to transport GMOs shall be labeled with a Transport Label with an address of the Receiver/Authorized Party (who shall be notified in case of accidental release), securely affixed to the outside of the tertiary container.

d) Tertiary containers may not be applicable to large sized GMOs; hence clarification shall be sought from regulatory Authority.

e) Documentation for the Transport must accompany the GMOs.

f) Where primary containers of seed of multiple events may be included within a single secondary container, a Transport Inventory List shall be affixed to the Record of Transport.

g) The following documents shall be signed, dated and secured to/within containers by the Shipper:
    - The original Record of Transport, with attached Transport Inventory List where applicable and other accompanied documents shall be placed within the secondary container.

- Copies of all accompanying documents (Plant Import Permit, Phytosanitary Certificate, Pesticides Registration etc) shall be retained by the Shipper in the shipment facility's Compliance Document Binder.

2.1.3 Receipt of shipment

Careful verification of receipt is critical to maintaining valid documentation and preventing inadvertent release of GM material. The receiving party shall observe the following requirements upon receipt of shipment:

a) Verify that the Record of Transport accompanying the shipment was duly signed by the Shipper.

b) If the original Record of Transport, and Transport Inventory List where applicable, are absent from the shipment, the Receiver shall contact the Shipper and inform the Authorized Party and the Regulatory Authority and request copies be transmitted immediately.

c) Until such time as the original Record of Transport documents are received and the inventory confirmed, the materials shall be securely stored and no further action shall be taken with the materials.

d) Complete the Receipt of Shipment section of the original Record of Transport, including the confirmation that the containers used for transport were not breached.

e) If the tertiary container (where applicable) was breached but the secondary container remained secure no further action is required.

f) If both the secondary and tertiary containers (where applicable) were breached ensure that the primary container was not breached and that none of the seed and/or plant material has been lost by confirming the weight of the shipment or number of plants/transplants.

g) If it cannot be assured that an accidental release of plant material has occurred, treat this as a case of accidental release and immediately notify the Authorized Party who will initiate appropriate reporting to the Regulatory Authority immediately for corrective actions.

h) If the consignment arrived intact the Receiver shall inform the Shipper, the Authorizing party and Regulatory Authority and the record shall be kept in the Compliance Document Binder.

2.1.4 Record Keeping

a) Copies of the Record of Transport and Transport Inventory List as completed by the Receiver shall be forwarded to the Shipper, the Authorized Party, and Regulatory

Authority and the original copy shall be inserted in the Trial Manager's Compliance Document Binder.

b) The Compliance Document Binder shall be available for inspection by the regulatory officials upon request.

2.2 Standard operating procedures for storage

All GMOs must be stored and maintained to preserve its identity, security and integrity, and to prevent it from being consumed by humans, livestock or other animals. The Trial Manager for confined field trials of GMOs shall ensure good condition of storage facilities on site prior to accepting the shipment of GMOs. To achieve these goals, the following should be observed:

2.2.1 General Requirements for Storage of GMOs

a) A storage area shall be a fully enclosed space (e.g. filing cabinet, office closet). Access doors shall be lockable. Windows shall be closed and locked.

b) A storage area for GMOs shall be used exclusively for such articles.

c) Where a storage area may be used to store multiple samples of one or more GMOs and plant products, each sample shall be stored separately.

d) All storage areas shall be clearly labeled as containing GM plant materials.

e) Access to storage areas shall be limited to personnel authorized by the Trial Manager.

f) Areas or units designated for storage of GM plant materials shall be sanitized prior to, and immediately following the period of storage.

g) Any GM plant sample withdrawn from storage for purpose of disposal shall be destroyed by dry heat, steam heat, crushing, burning, autoclaving or treatment with appropriately registered herbicides and/or chemicals.

h) A storage area shall be labeled as containing GM plant materials.

i) The storage area label (Figure 3) shall be affixed to the point of access to the storage area.

2.2.2 Inspection of the Storage Area

a) A record of storage inspection shall be completed monthly by the Facility Manager to ensure that storage conditions are maintained in accordance with this SOP.

b) The Record of Storage Inspection shall be maintained by the Facility Manager in the storage facility's Compliance Document Binder.

c) Access to the storage area for the purpose of inspection shall be provided to Regulatory Authority officials upon request provided they present official identification and the inspection is undertaken during regular business hours.

2.2.3 Record Keeping

a) The Trial Manager shall retain the Record of Storage Inspection in the storage facility's Compliance Document Binder.

b) The Compliance Document Binder shall be available for inspection by the Regulatory authority officials upon request.

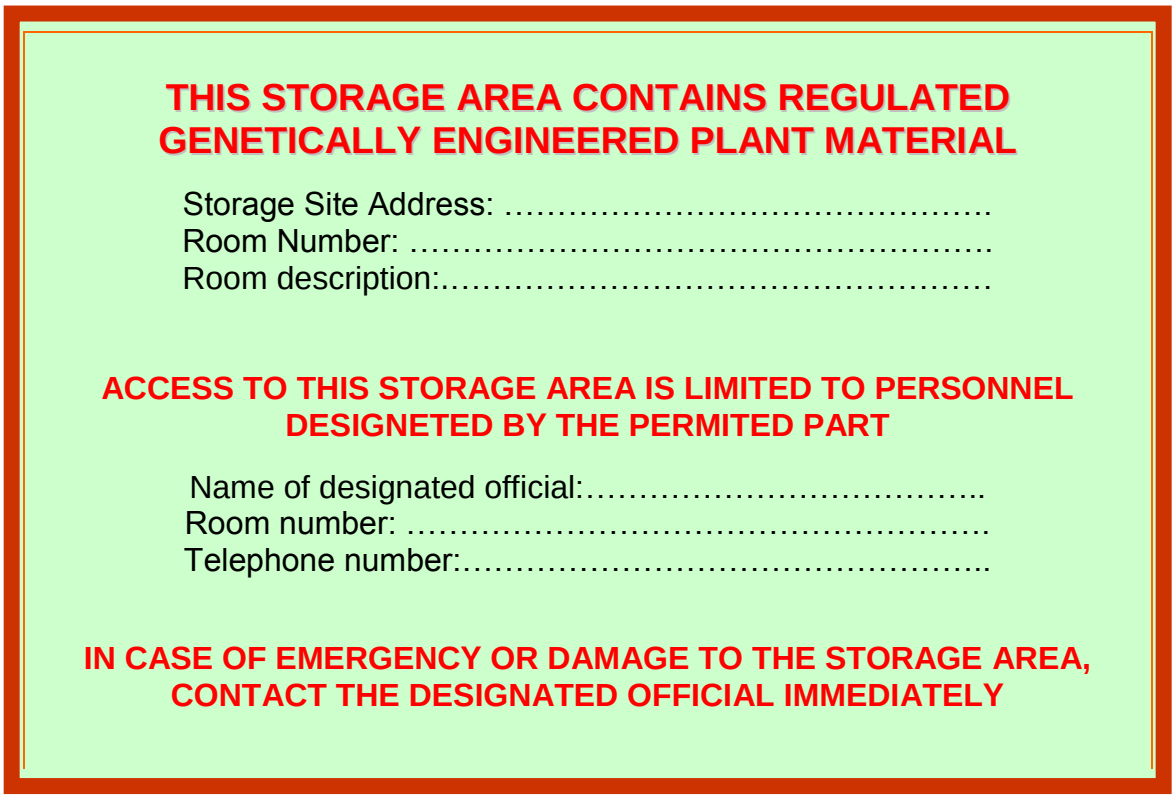

Figure 3: Sample storage area label

2.3 Standard operating procedures for current season field trial

2.3.1 Notification

The authorized party shall inform Regulatory Authority in writing two (2) weeks prior to planting for the Inspectors to supervise the planting. The first inspection of the field trial by the Regulatory Authority will be carried out one (1) month after planting.

2.3.2 Security

All sites used for testing of GM plants in Tanzania are required to have adequate security (Figure 4), in order to safeguard the GM material and to prevent it from being consumed by humans, livestock and other animals. All sites shall have provisions for limiting access to authorized personnel, and of restricting the site from incursion by livestock or other animals. Proposed sites shall be inspected by Biosafety inspectors or other regulatory agents for compliance with this provision as a condition of trial authorization.

Figure 4: Confined field trial with fence

2.3.3 Equipment

a) All equipment used to seed or plant GMOs shall be free of any plant material before entering the trial site.

b) All equipment used to seed or plant GMOs or in the maintenance of the trial site shall be cleaned on the trial site and recorded to eliminate unintended transport of GMOs away from the trial site. Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water.

c) Disassembly may be required when necessary to verify that the equipment is free of propagative plant material.

d) Any residual plant material recovered during the process of cleaning field equipment shall be destroyed by crushing, deep burial, dicing into the soil, burning, or treatment with appropriately labeled herbicides and/or chemicals and disposed of on the trial site.

e) All planting equipment shall be inspected after cleaning and verified to be free of preparative plant material by trial personnel.

2.3.4 Trial map/site

A map of the trial site (Figure 5) shall be prepared by the Trial Manager within 48 hrs of completion of plating and appended to the Record of Planting.

2.3.5 Record of planting

A record of planting shall be completed for each field trial site. A copy of the record of planting, with appended map, shall be submitted to Regulatory Authority by the Authorized party within 5 working days of planting, and the original shall be retained by the Trial Manager in the Compliance Document Binder

2.3.6 Identification of trial sites and plots

a) All four corners of each trial site shall be clearly marked with permanent markers suitable to permit identification of the trial site during both the growing season and the mandated period of post-harvest land use restriction (e.g. fence post, PVC piping).

b) Global positioning system (GPS) coordinates may be recorded at all four corners of each trial site and shall be obtained using GPS instrumentation.

2.3.7 Reproductive isolation

To prevent the escape of genes in pollen (pollen-mediated gene flow) from the trial site, all field trial sites of GMOs shall be reproductively isolated from any sexually compatible species; sub-species or varieties that are not part of the trial (Figure 6).

Sexually compatible plants are called ‘prohibitive plants’, and are described in detail in the Terms and Conditions of authorization of each trial. The techniques used vary with the particular crop species, some of which are described below.

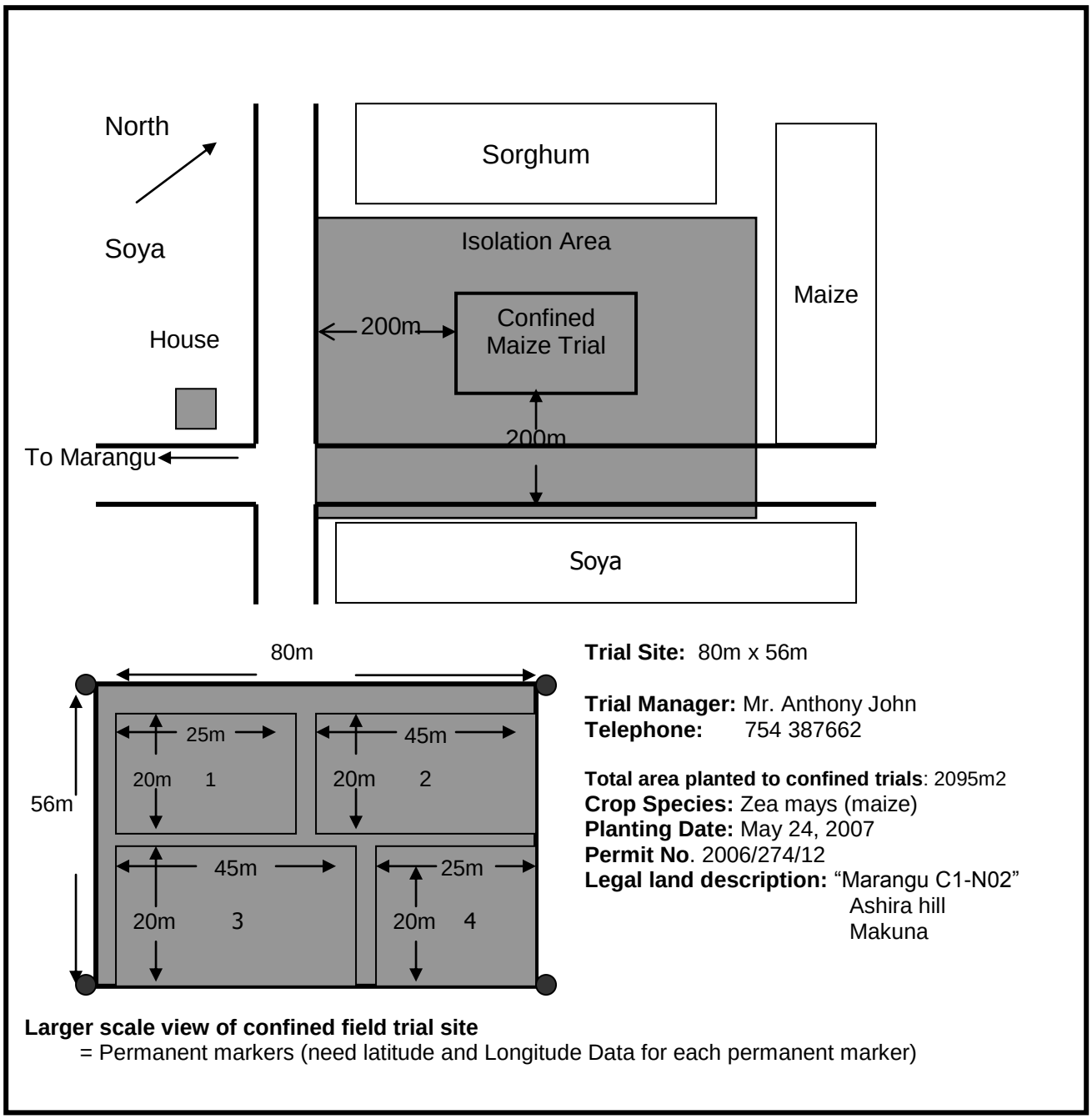

Figure 5: Example of properly prepared map of CF trial of GM cotton

a) Spatial isolation of confined field trial sites

Enforcing a spatial isolation distance is the primary means of assuring reproductive isolation. Isolation distances are derived from observations and experiments of plant breeders. The Ministerial competent authority shall provide the appropriate isolation distances recommended for specific crops. The Trial Manager shall monitor the spatial isolation distance. All prohibited plants shall be removed prior to flowering to avoid a potential breach of reproductive isolation occuring.

b) Early Crop Destruction

Where the objectives of a particular trial may be achieved before the GM plants flower, early crop destruction may be used as a means of reproductive isolation. In this case, the Trial manager shall document and verify that the GM plants were destroyed prior to any release of pollen.

Early Crop Destruct may be used as an alternative method of reproductive isolation. The intention for application of this method must be mentioned in the application for approval. Early Crop Destruction/harvesting of GMOs shall be conducted in the trial site prior to the emergence of inflorescence (flowers). Early Crop Destruct may be conducted after getting an authorization from regulatory authorities

The Authorized party shall inform regulatory authorities in writing 2 weeks before the intended date of early crop harvest/destruction.

An Inspector of the Regulatory Authority will supervise the process of early harvest/destruction of the GMOs in the trial site.

c) Removal of Flowers Prior to Pollen Shed

Where male flowers may be readily identified prior to pollen production, as in the case of maize (*Z. mays*), cassava (*M. esculenta*) and banana (Musa sp), these flowers may be removed prior to pollen production. Frequent inspection, as specified in Table 1, is required to ensure that all male flowers are removed, thus verifying that no pollen was shed.

d) Prevention of Viable Pollen Production or Release

The production of viable pollen may be prevented through genetic means such as male sterility, or the release of pollen may be prevented by physical means such as the bagging of male flowers (tassels) in maize. Where these techniques are proposed as the primary means of reproductive isolation for a confined field trial, the applicant is required to submit justification and detailed methodology to support the proposal.

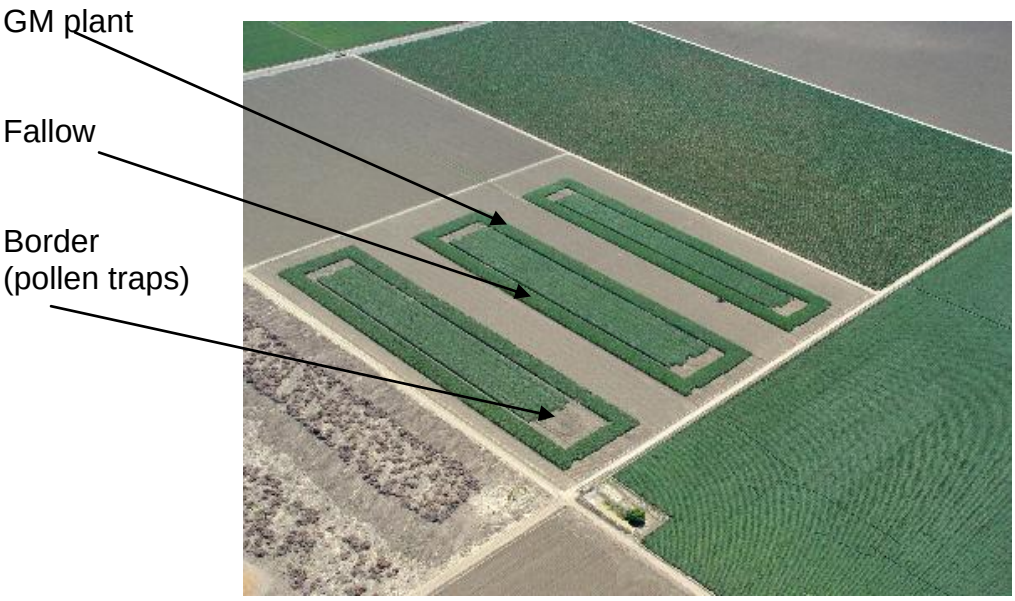

Figure 6: Confined Field trial of GM cotton showing reproductive isolation

e) Border rows

Establishment of Border rows (pollen-trap rows) is appropriate in crops that are insect-pollinated, such as cotton (*G. hirsultum*) and cassava (*M. esculenta*). The border rows attract pollinating insects thus limiting the spread of GM pollen.

To be effective, plants in the border rows must flower at the same time as the GM plants and be of approximately the same grown habit and stature. Border rows must completely surround the GM trial site on all sides, and must not have any continuous gap (alley way or pathway) transversing the border rows. The trial Manager shall document that the border rows are intact and that the GM plants and border rows have a similar flowering period and growth habit.

When border rows are used for genetic isolation, the exterior of the plot, measured from the outside of the border rows, shall be a minimum distance from any prohibited plants as a secondary mechanism of reproductive isolation. The entire area including the border rows shall be considered to be the 'plot area' for purposes of post-harvest restriction and volunteer monitoring.

To ensure that the highest degree of confinement is attained, the minimum isolation distance is always required, regardless of any additional alternative methods of reproductive isolation.

2.3.8 Breach of reproductive isolation

Breach of reproductive isolation is an extremely serious incident, and shall be reported to Regulatory Authority according to instructions found herein. The Authorized Party may be required by the Regulatory Authority to destroy the field trial or any prohibited

plants within the spatial isolation distance immediately. The Authorized Party shall be responsible for any legal or financial consequences resulting from breach of reproductive isolation. Remedies for specific instances of breach of reproductive isolation are described below.

a) Breach of Alternative Methods of Reproductive Isolation

Where any alternative method of reproductive isolation mentioned here has occurred, the minimum spatial isolation distance becomes the default method of reproductive isolation, and the Authorized Party shall be required to enforce accordingly.

b) Breach of Spatial Isolation Distance

Where prohibited plants are allowed to flower within the spatial isolation distance, these plants must be destroyed. In this case, the post-harvest restriction and monitoring requirements may be made more stringent and the period of post-harvest monitoring may be extended, at the discretion of the Regulatory Authority.

c) Termination due to Breach Reproductive Isolation

Where reproductive isolation of the GMOs cannot be re-established by spatial isolation, the trial shall be terminated.

Table 1: Alternative Methods of Reproductive isolation

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	3m (3rows) 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	12m 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 they fully emerge, prior to pollen shed.

2.3.9 Monitoring of the Field Trial by the Trial Manager

The Authorized Party shall design a monitoring program adequate to ensure compliancy to the biosafety SOPs.

a) The Trial Manager, or a person so designated for this purpose by the Trial Manager, shall inspect and make record of the trial site every 2 weeks from the time of planting until the time of harvest.

b) The Record of Spatial Isolation shall be used to document all inspection activities needed to ensure spatial reproductive isolation of the trial site.

c) Where spatial isolation is used for reproductive isolation, the growth stage of any prohibited spp. shall be recorded during inspection.

d) When reproductive isolation is achieved using border rows, inspection of border rows shall be undertaken every week from the time the first inflorescence emerges on the first bloom until the termination of pollen shed by the GM plants. Following inflorescence emergence and until all GM plants have completed anthesis, trials should be inspected daily.

e) Non-Target Effects on the GM Plants: Monitoring for specific non-target effects may be required, depending on the crop and genetic modification in the trial. The Authorized Party may suggest a monitoring program for non-target pests, diseases or for environmental impacts, including details in the Application for Confined Field Trial, or elements of non-target monitoring may be required as a condition of authorization by the Regulator.

2.3.10 Inspection of the Field Trial by Regulatory Officials

Access to the trial site for the purpose of inspection shall be provided to the regulatory official so long as the inspection is undertaken during regular business hours.

2.3.11 Occurrence of Non-Compliance

a) The Trial Manager and/or the Authorized party shall notify the regulatory authorities immediately of all situations where reproductive isolation of the trial site has been breached.

b) In case of accidental release at any location, the Trial Manager and/or the Authorized party shall immediately notify regulatory authorities orally, and confirm such in writing within 24 hours.

c) The Regulatory authority shall determine the subsequent course of action.

2.3.12 Record Keeping

a) The record of planting and map of each trial site shall be retained by the Trial Manager in the Compliance Document Binder and one copy shall be submitted to the Regulatory authority and the Authorized party within 48 hours of planting.

b) The Record of Spatial Isolation for each trial site shall be retained by the Trial Manager in the Compliance Document Binder.

c) The Record of Guard Row Isolation for each trial site shall be retained by the Trial Manager in the Compliance Document Binder

d) The Compliance Document Binder shall be available for inspection by regulatory officials upon request.

2.4 Standard operating procedures for harvest termination and disposal

The following requirements are to be applied to the harvest of trial sites of GMOs including trial sites that may be prematurely terminated prior to the anticipated harvest date (e.g. due to seasonal changes and hence, premature ripening).

2.4.1 General requirements for Harvest of Trial Sites

a) No plant materials from the trial site, including non-GM materials from border rows, shall enter the human food or animal feed chains.

b) All equipment used to harvest at the trial site shall be free of plant material before entering the trial site, including seed and vegetative material that may be present from prior operations.

c) All equipment used to harvest a trial site shall be cleaned and recorded on the trial site to eliminate unintended transport of GMOs from the site. Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water.

d) No any GM plants and plant products from the trial site shall be retained by the Authorized party without prior authorization from Regulatory Authority

2.4.2 Early Termination of Trial Sites

a) Trial sites that are terminated before seed set shall be destroyed and subsequently plowed under or treated with appropriately labeled herbicides and/or chemicals to render the plant materials non-viable.

b) Post-harvest restrictions shall apply to trial sites that are terminated early as seed of the GMOs may remain from planting and volunteer in subsequent years.

c) All activities related to early termination of a trial site shall be recorded in the Record of Harvest/Termination

d) The Authorized party shall inform the Regulatory Authority 14 days before the expected date of the early harvest so that Inspectors be present at the time of harvest.

2.4.3 Destruction of GMOs

a) Plant material from a trial site, including border rows, that is not retained for research purposes shall be destroyed by crushing, deep burial, discing into the soil, burning, autoclaving, incinerating, or treatment with appropriately registered herbicides and/or chemicals and disposed of on the trial site. Where deep burials are used, the depth must be sufficient to prevent accidental exposure of the material or the emergence of living plants. In most cases, a depth of 1m of soil covering the top of the plant material is sufficient to achieve these goals.

b) The Trial Manager or his/her designate shall monitor harvesting at trial sites to ensure that GMOs that are not retained are disposed.

2.4.4 Packaging, and shipping of Harvested Materials from the Trial Site

All GM plant materials harvested from a trial site and retained shall be secured during shipping from the trial site to the receiving facility to prevent any accidental release. Transport of harvested GM materials shall be done as per SOPs of shipping.

2.4.5 Occurrence of Non-Compliance

a) The Trial Manager and/or the Authorized party shall notify Regulatory authority of all situations where harvest restrictions for the trial site have been breached.

b) In case of any accidental release at any location, the Trial Manager and/or the Authorized party shall immediately notify Regulatory authority orally, and confirm such in writing within 24 hours. Regulatory authority shall determine any subsequent course of action.

2.4.6 Corrective Action in Case of an Accidental Release

Any incidents of unintentional release arising from harvest activities are subject to the reporting requirements as described in the Accidental release SOP.

2.4.7 Record Keeping

Details of Harvest/Termination and Disposition shall be recorded by the Trial Manager immediately following harvest or early termination of a trial site. One copy shall be retained by the Trial Manager in the Compliance Document Binder and one copy shall

be submitted to the Authorized Party and to Regulatory authority within 5 days of harvest or early termination.

2.5 Standard operating procedures for Post-Harvest Management

2.5.1 Post-harvest land use restriction

Trial sites of Genetically modified (GM) plants shall be subject to a period of post-harvest land use restriction and post harvest monitoring. These requirements allow volunteers of the GM plant to be identified and destroyed. The guard rows are also included in the post harvest monitoring. But if some part of the border row broke down during the field trial, post harvest monitoring will also include the recommended isolation distance.

2.5.2 Post-harvest monitoring period

a) The post-harvest monitoring period begins immediately upon harvest of the trial site or termination of the trial site for any other reason.

b) The area under restriction must be monitored during the post-harvest period to ensure that any prohibited plants are destroyed prior to flowering.

c) No plants of the same or a sexually compatible species may be planted in the restricted area during the post-harvest period.

d) The Authorized Party shall seek authority in writing at least 30 days in advance of planting any plant species on the trial site during the post-harvest period.

2.5.3 Post-harvest monitoring

a) During the post-harvest period, any harvested plant materials from the trial sites shall not enter the human food or animal feed chain.

b) The Regulatory Authority shall ensure that Authorized Party maintain ownership and/or control of the trial site during post-harvest period. This assurance shall be obtained before the trial site is planted.

c) Where the trial site will not be used for subsequent cultivation of GM plant. The Trial Manager shall ensure that no prohibited plant spp. is cultivated on the trial site (which includes the border row area). This restriction also applies to the isolation distance when included for post-harvest monitoring.

2.5.4 Destruction of volunteers

a) The Trial Manager shall ensure that the trial site is inspected for the presence of volunteers or sexually compatible species no less than once every two weeks during the period that post-harvest land use restrictions.

b) During the post-harvest period, all volunteers and other prohibited plants shall be removed from the trial site before anthesis, destroyed by crushing, deep burial, discing into soil, burning, or treatment with appropriately registered herbicides and/or chemicals, and disposed off. The disposal of the volunteers by any of the above shall be done at the trial site.

2.5.5 Breach of Spatial Isolation during the Season

Where there has been an established breach of spatial reproductive isolation distance during the season – where prohibited plants have been allowed to flower within the spatial isolation distance – the spatial isolation distance shall also be subject to post-harvest restriction and monitoring requirements described in this SOP.

2.5.6 Destruction of Volunteers

a) Volunteers shall be destroyed before flowering, and shall be disposed of within the trial site in a fashion that prevents consumption by humans, livestock or other animals.

b) Appropriate methods of destruction include chemical treatment, cultivation into the soil or herbicides for devitalization. If volunteers are allowed to flower within the trial site, this constitutes a serious breach of compliance.

2.5.7 Equipment

All equipment used to destroy volunteers on a confined field trial site shall be cleaned of plant material before being moved from the trial site. Appropriate cleaning methods include manual removal or plant material, brushing, compressed air, vacuuming or water. All such equipment shall be inspected after cleaning and verified to be free of plant material by trial personnel.

2.5.8 Non-Compliance

a) Where there has been an established breach of compliance with these requirements, the post-harvest restriction shall be extended for an additional post-harvest monitoring period.

b) If prohibited plants are present in the spatial isolation distance at the time of flowering of the volunteers, and there is a possibility that they may have cross-pollinated with the volunteers, then the post-harvest restriction shall extend to the spatial isolation distance required for the GM plants.

c) The Authorized Party shall be responsible for any legal or financial obligations incurred due to any incident of non-compliance.

2.5.9 Records and Reports

a) Details of post-harvest management of the trial site, including monitoring and destruction of volunteers and establishment of any following crop shall be recorded by trial personnel. An example of an appropriate Volunteer Monitoring Form may be found in the Report Formats Section.

b) The Authorized Party shall submit a Final Report within six (6) months after the completion of the post-harvest period.

2.6 Standard operating procedures for Corrective Action in Case of an Accidental Release

2.6.1 Notification

In case of any accidental release the Shipper/Receiver or trial manager shall immediately within one (1) hour notify the Authorized Party or the applicant who shall immediately notify the Regulatory Authority in writing within 24 hours of the accidental release.

2.6.2 Recovery

In case of any accidental release of a GMOs, all attempts shall be made to recover as much of the GMOs as possible and destroyed.

2.6.3 Site location and monitoring

The location of an accidental release shall be marked and monitored and shall be treated in a manner that ensures that no additional release of material occurs. The period for monitoring shall be determined by Regulatory Authority.

2.6.4 Documentation

The accidental release of GMOs shall be immediately documented by the Shipper/Receiver/ Trial manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Trial manager/Receiver and copies shall be submitted by facsimile to the Authorized Party/applicant who shall inform Regulatory Authority immediately.

2.7 Standard operating procedures for submission of CFT report

2.7.1 Submission of reports

All reports shall be submitted by regular mail, courier, facsimile, or electronically to the Regulatory Authority designated by the respective MCA.

All reports shall reference the Authorization Code Number assigned to the trial and use the recommended Forms (see Section 3). Reports required are described in the sections below.

2.7.2 In-Season Reports

The following reports are required during the conduct of the trial.

a) Trial Establishment Report

The authorized Party shall submit details of site establishment within five (5) working days after the completion of planting at the site. The report will include the planting date, the amount of material planted, disposal and storage of any surplus GM plant material remaining after planting, and the size of the trial site. A final field site map shall also be submitted at this time.

b) Trial Progress Report

The Authorized Party shall submit a progress report after completion of the flowering period of the crop. The report will include flowering information and results of activities enforcing reproductive isolation.

c) Harvest Report

The Authorized Party shall submit details of site harvest within five (5) working days after the completion of harvest at the site. The report will include the date and method of harvest, the storage or disposal of any harvested materials, and the method of destruction of any residual plant material on the site.

2.7.3 Other Reports

The following reports are required in the unusual circumstances described below.

a) Incident and Corrective Action Report

The Authorized Party shall orally notify the Regulatory Authority immediately, and in writing within 24 hours, of any incident involving an accidental or unauthorized release of Genetically modified plant material. The report will include any corrective actions taken or planned to contain GM material and ameliorate the incident.

b) Unanticipated Effects Report

The Authorized Party shall notify Regulatory Authority in writing within five (5) working days if the GM plants exhibit any substantial unanticipated characteristics or effects, or if any unusual event occurs that may jeopardize the confinement of the GM plants.

2.7.4 Final Reporting

The following summary reports are required for each confined field trial.

a) Interim Report

The Authorized Party shall submit an Interim Report within six (6) months after the harvest or termination of the trial summarizing observations and data, methods of observation and analysis of experimental result concerning the trial and any unanticipated effects.

b) Final Report

The Authorized Party shall submit a final report within six (6) months after the completion of the post-harvest period summarizing the completed trial including observation and data, methods of observation and analysis. The content shall include but not limited to the following: Shipping, receiving, storage, planting, trial management during current season including maintenance of reproductive isolation termination of harvest, final disposal of GM plant materials, post harvest monitoring, and corrective measures in case of accidental or unintended release. Any non compliance shall also be reported and any measures taken to bring the trial back to compliance.

2.7.5 Compliance Document Binder

a) A compliance document binder shall be prepared to document all steps of the confined field trial such as shipping, storage, field-testing, harvest, and post harvest monitoring of Genetically modified (GM) plants and plant products.

b) The compliance document binder shall include: manual for safe conduct of confined field trials, Standard Operating Procedures (SOPs), Records and Reports.

3.0 REPORTS AND RECORD FORMS

3.1 Introduction

Adequate records are critical to establish the compliance of the Authorized Party with the Terms and conditions of authorization and other relevant requirements. Clear, authentic and readily accessible records shall be maintained to document critical activities. NBFP therefore publishes the attached example forms, which may be used by the Authorized Party for guidance in developing forms for use in their specific confined trials.

3.2 Instructions for Completing Forms and Documents

i) Record information directly, promptly and legibly with blue or black pen or electronically. Do not use pencil or whiteout. Capitalize written information.

ii) Date format is Day, Month, Year. Use metric (SI) units such as kg. m. ha for information.

iii) If there is not enough space on a page to record all data or explanations needed, add extra pages and complete the entry there.

iv) Areas left blank for any reason must be lined-out, initialed and dated.

v) It is acceptable to carry identical information down through a column by use of a line drawn between the first entry and the same entry repeated in the last space of the column.

vi) Changes to entries should be made by drawing one line through the original entry so as not to obscure it, indicate the reason for the change, then initial and date entry.

3.3 Examples of Recommended Report forms

3.3.1 Report forms for Shipping of Genetically modified Plants

SHIPPER	**RECEIVER**
Name:	Name:
Title/Organization:	Title/Organization:
Address:	Address
Phone/Fax:	Phone/Fax:
Email:	Email:

SHIPPING INFORMATION

	Shipped		Received	
Item	Amount	By	Amount	By
Total				

Packaging description		Shipper signature	
Conveyance		Conveyor Initial signature	
Depart [origin]	Date	Time	
Arrive [origin]	Date	Time	

RECEIVEING INFORMATION

Note: Receiver records following Information and 'received' columns above.

Received on (date/time)	Received and checked by (print):
Title and location of receiver:	
Total [amount] received:	Phytosanitary permit enclosed? Yes/No
Notes on condition upon receipt (damaged containers, etc):	
Storage/transport receipt:	
Receiver signature	Date:

3.3.2 Report forms for Storage of Genetically modified Plant Material

<table>
<tr><td colspan="4">INVENTORY CONTROL MANAGER</td><td colspan="3">GENETICALLY MODIFIED PLANT IDENTIFICATION</td></tr>
<tr><td colspan="2">LAST NAME</td><td colspan="2">FIRST NAME MI</td><td>USER ID NUMBER</td><td colspan="2">CFT PERMIT No.</td></tr>
<tr><td colspan="2">COMPANY/ORGANISATION</td><td colspan="2">DEPARTMENT/SECTION</td><td>PLANT SPECIES</td><td colspan="2">SPECIFY EXACT AMOUNT OF MATERIAL SHIPPED</td></tr>
<tr><td colspan="4">POSTAL ADDRESS</td><td>FORM OF MATERIAL</td><td colspan="2">IDENTIFY ANY SEED TREATMENT OR OTHERTREATMENT OF THE MATERIAL</td></tr>
<tr><td>TELEPHONE</td><td>FACSIMILE</td><td colspan="2">E-MAIL</td><td></td><td colspan="2"></td></tr>
<tr><td colspan="4">STORAGE FACILITIES</td><td colspan="3">INVENTORY INFORMATION</td></tr>
<tr><td colspan="2">BUILDING NAME OR ID</td><td colspan="2">ROOM NUMBER OR DESCRIPTION</td><td>AMOUNT OF MATERIAL PLACED INTO STORAGE</td><td>DATE STORED (DD/MM/YY)</td><td>STORAGE LOCATION IDENTIFIER</td></tr>
<tr><td colspan="4">PHYSICAL ADDRESS</td><td colspan="2">CREATION OF RECORD OF STORAGE

…….
SIGNATURE OF INVENTORY CONTROL MANAGER</td><td>EFFECTIVE DATE (DD/MM/YYY)

……</td></tr>
<tr><td colspan="7">TERMINATION OF RECORD STORAGE</td></tr>
<tr><td colspan="2">SEASON FOR TERMINATION OF STORAGE
□ ALL MATERIAL REMOVED
□ DESTRUCTION OF MATERIAL
□ OTHER (below)</td><td colspan="4">SIGNATURE OF INVENTORY CONTROL MANAGER

……</td><td>EFFECTIVE DATE (DD/MM/YYYY)</td></tr>
<tr><td colspan="7">INSTRUCTIONS

This Record of Storage should be completed for each Genetically modified (GM) plants and plant products placed into storage and each Record of Storage should be identified with a unique inventory number. One or more copies of the Record of Inventory can be attached to the Record of Storage to document any removals of material from storage</td></tr>
</table>

3.3.3 Report forms for border row isolation

TRIAL MANAGER			**TRIAL SITE**	
LAST NAME	FIRST NAME	MI	SITE LOCATION	
COMPANY/ORGANIZATION/INSTITUTION	DEPARTMENT/SECTION		TRIAL SIZE(MXM)	No. OF TRIALS AT THIS SITE
POSTAL ADDRESS			LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE	
			DISTANCE TO NEAREST NON-GENETICALLY MODIFIEDCROP FIELD (M)	DISTANCE TO NEAREST COMMERCIAL CROP OF ANY KIND (M)
TELEPHONE	FACSIMILE	E-MAIL	IS THE ISOLATION DISTANCE UNDER THE MANAGER'S CONTROL? □ YES □ NO	
BORDER ROW ISOLATION VARIETY(IES) USED FOR GUARD ROW		DATE PLANTED (DD/MM/YY)	WAS THERE COMPLETE GERMINATION OF THE BORDER ROW? □ YES □ NO	
IF GERMINATION IS INCOMPLETE, DESCRIBE CORRECTIVE ACTION TAKEN TO FILL GAPS				

GENETICALLY MODIFIED PLANTS UNDER TRIAL					
CFT PERMIT/ NOTIFICATION No.	CFT PERMIT/ NOTIFICATION No	CFT PERMIT/ NOTIFICATION No	CFT PERMIT/ NOTIFICATION No	CFT PERMIT/ NOTIFICATION No	CFT PERMIT/NOTIFICATION No

DATA SHEET FOR RECORDING INSPECTIONS AND CROP DESTRUCTION						
DATE INSPECTED (DD/MM/YY)	GROWTH STAGE OF TRIAL PLANTS	TRIAL PLANTS IN FLOWER? □[YES] □ NO]	GROWTH STAGE OF TRIAL PLANTS	TRIAL PLANTS IN FLOWER? □ YES □[NO]	ADDITIONAL COMMENT AND OBSERTIONS	INSPECTOR'S SIGNATURE

DATA SHEET FOR RECORDING INSPECTIONS AND CROP DESTRUCTION						
DATE INSPECTED (DD/MM/YY)	GROWTH STAGE OF TRIAL PLANTS	TRIAL PLANTS IN FLOWER? □ YES □ NO	GROWTH STAGE OF TRIAL PLANTS	TRIAL PLANTS IN FLOWER? □ YES □ NO	ADDITIONAL COMMENT AND OBSERTIONS	INSPECTOR'S SIGNATURE

ADDITIONALCOMMENTS AND OBSERVATION		
TRIAL MANAGER VERIFICATION THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	SIGNATURE OF TRIAL MANAGER …… BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF	DATE SIGNED (DD/MM/YYYY)

INSTRUCTIONS

- When productive isolation is achieved using border rows, inspection in the trial and border rows shall be undertaken EVERY WEEK from the time the inflorescence emerges until the termination of pollen shed by the GM plants. Following inflorescence emergence and until all GM plants have been completed anthesis, trials should be inspected DAILY.
- The accidental release of a GM plant and in case of any corrective action taken, shall be immediately documented in a Record of Corrective Action.
- The original record shall be retained by the Trial Manager, and copies shall immediately be submitted by facsimile to Regulatory Agency and the authorized part.

3.3.4 Report forms for spatial isolation

TRIAL MANAGER			**TRIAL SITE**	
LAST NAME	FIRST NAME	MI	SITE LOCATION CODE	
COMPANY/ORGANIZATION	DEPARTMENT/SECTION		TRIAL SIZE(MXM)	No. OF TRIALS AT THIS SITE
POSTAL ADDRESS			LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE	
			DISTANCE TO NEAREST GENETICALLY MODIFIEDCROP FIELD (M)	DISTANCE TO NEAREST COMMERCIAL CROP OF ANY KIND (M)
TELEPHONE	FACSIMILE	E-MAIL	IS THE ISOLATION DISTANCE UNDER THE MANAGER'S CONTROL? ☐ YES ☐ NO	

GENETICALLY MODIFIED PLANTS UNDER TRIAL					
REFERENCE No.	CFT/AUTHORIZATION PERMIT No.	DATE PLANTED (DD/MM/YY)	REFERENCE No.	CFT/AUTHORIZATION PERMIT No.	DATE PLANTED (DD/MM/YY)

DATA SHEET FOR RECORDING INSPECTIONS FOR THE PRESENCE OF PROHIBITED PLANTS				
DATE INSPECTED (DD/MM/YY)	PROHIBITED PLANTS PRESENT ☐ YES ☐ NO	GROWTH STATE OF ANY PROHIBITED PLANTS	ADDITIONAL COMMENTS AND OBSERVATIONS	INSPECTOR'S SIGNATURE

DATA SHEET FOR RECORDING INSPECTIONS FOR THE PRESENCE OF PROHIBITED PLANTS				
DATE INSPECTED (DD/MM/YY)	PROHIBITED PLANTS PRESENT ☐ YES ☐ NO	GROWTH STATE OF ANY PROHIBITED PLANTS	ADDITIONAL COMMENTS AND OBSERVATIONS	INSPECTOR'S SIGNATURE

VERIFICATION		
THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	SIGNATURE OF TRIAL MANAGER …… BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.	DATE SIGNED (DD/MM/YYYY)

INSTRUCTIONS
This **Record of Spatial Isolation** Should be retained by the **Trial Manager** and made available to **Regulatory Authority**

inspectors upon request.

3.3.5 Report forms for harvest/termination and disposition

TRIAL MANAGER			**TRIAL SITE**	
LAST NAME	FIRST NAME	MI	SITE LOCATION CODE	
COMPANY/ORGANIZATION	DEPARTMENT/SECTION		TRIAL SIZE(MXM)	No. OF TRIALS AT THIS SITE
POSTAL ADDRESS			LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE	
			REASON FOR TERMINATION ☐ **EARLY TRIAL TERMINATION** ☐ **END OF SEASON HARVEST**	IF TERMINATED EARLY, WAS IT BECAUSE OF A NON-COMPLIANCE ISSUE? ☐ YES ☐ NO
TELEPHONE	FACSIMILE	E-MAIL	IS THE ISOLATION DISTANCE UNDER THE MANAGER'S CONTROL? ☐ YES ☐ NO	

HARVESTING MACHINERY	
METHOD USED FOR HARVEST ☐ MACHINERY ☐ BY HAND ☐ OTHER (below)	WAS ALL MACHINERY INSPECTED AND CONFIRMED FREE OF PLANT MATERIAL PRIOR TO ENTERING THE TRIAL SITE? ☐ YES ☐ NO
TYPE OF MACHINERY USED FOR HARVEST	INDICATE HOW MACHINERY WAS CLEANED AT THE TRIAL SITE FOLLOWING CROP DESTRUCT

ON-SITE DESTRUCTION OF PLANT MATERIAL

INDICATE THE METHOD OF DESTRUCTION OF GENETICALLY MODIFIED PLANTS AT THE TRIAL SITE (DESCRIBE IN DETAIL BELOW)
☐ AUTOCLAVING ☐ INCINERATING ☐ BURNING ☐ DISCING ☐ PLOWING ☐ DEEP BURIAL ☐ CHEMICAL ☐ OTHER (below)

DATA SHEET FOR RECORDING HARVEST AND DISPOSITION

REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	AMOUNT HARVESTED (KGs)	QUANTITY RETAINED/STORED (KGs)	HARVEST DATE	TYPE OF MATERIAL RETAINED ☐ GRAIN/SEED ☐ VEGETATIVE MATERIAL ☐ WHOLE PLANTS
GENETICALLY MODIFIED PLANTS SHIPPED FROM SITE ☐ YES ☐ NO	SHIPMENT No.	GENETICALLY MODIFIED PLANTS STORED ON SITE ☐ YES ☐ NO	FACILITY CODE	INVENTORY CONTROL No.	

AUTHORIZATION BY REGULATORY AUTHORITY

AUTHORIZATION FOR RETAINING PLANT MATERIAL RECEIVED FROM REGULATORY AUTHORITY ☐ YES ☐ NO

ADDITIONAL COMMENTS AND OBSERVATIONS

VERIFICATION THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	SIGNATURE OF TRIAL MANAGER BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.	DATE SIGNED (DD/MM/YYYY)

REGULATORY AUTHORITY VERIFICATION	SINGNATURE OF REGULATORY AUTHORITY/DESGNATED INSPECTOR ……	DATE SIGNED AND STAMP (DD/MM/YYYY) ……

INSTRUCTIONS

- This **Record of Harvest/Termination and Disposition** shall be completed by the **Trial Manager** immediately following harvest or early termination of a trial site. One copy shall be retained by the **Trial Manager** in the Compliance Document Binder and one copy shall be submitted to the Authorized party.
- This **Record of Harvest/Termination and Disposition** shall be verified by **Regulatory Authority Inspectors** who shall be present at the trial during harvest or early termination.

3.3.6 Harvest and crop destruction

TRIAL MANAGER			**TRIAL SITE**	
LAST NAME	FIRST NAME	MI	SITE LOCATION CODE	
COMPANY/ORGANIZATION/INSTITUTION	DEPARTMENT/SECTION		TRIAL SIZE	No. OF TRIALS AT THIS SITE
POSTAL ADDRESS			LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE	
			DISTANCE TO NEAREST GENETICALLY MODIFIEDCROP FIELD (M)	DISTANCE TO NEAREST COMMERCIAL CROP OF ANY KIND (M)
TELEPHONE	FACSIMILE	E-MAIL	IS THE ISOLATION DISTANCE UNDER THE MANAGER'S CONTROL? □ YES □ NO	
MACHINERY USED FOR CROP DESTRUCT			**ON-SITE DESTRUCTION OF PALNT MATERIAL** □ AUTOCALVING □ INCINERATING □ BURNING □ DISCING □ PLOWING □ DEEP BURIAL □ CHEMICAL TREATMENT □ OTHER (below)	
WAS ALL MACHINERY INSPECTED AND CONFIRMED FREE OF PLANT MATERIAL PRIOR TO ENTERING THE TRIAL SITE? □ YES □ NO				
DICATE HOW MACHINERY WAS CLEANED AT THE TRIAL SITE FOLLOWING CROP DESTRUCT □ VACUUMING □ COMPRESSED AIR □ HIGH-PRESSURE WATER □ OTHER (below)				

GENETICALLY MODIFIED PLANTS UNDER TRIAL

REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DATE PLANTED (DD/MM/YY)	REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DATE PLANTED (DD/MM/YY)

DATA SHEET FOR RECORDING INSPECTIONS AND CROP DESTRUCT

DATE INSPECTED (DD/MM/YY)	GROWTH STAGE OF TRIAL PLANTS	CROP DESTRUCT PERFORMED? □ YES □ NO □ COMPLETE	POLLEN SHED OBSERVED? □ YES □ NO	ADDITIONAL COMMENYS AND OBSERVATIONS	INSPECTOR'S SINGNATURE
		□ YES □ NO □ COMPLETE	□ YES □ NO		
		□ YES □ NO □ COMPLETE	□ YES □ NO		

DATA SHEET FOR RECORDING DISPOSITION

REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DESTRUCT DATE (DD/MM/YYYY)

ADDITIONAL COMMENTS AND OBSERVATIONS

TRIAL MANAGER VERIFICATION THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	SIGNATURE OF TRIAL MANAGER …… BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.	DATE SIGNED (DD/MM/YYYY) ……
REGULATORY AUTHORITY VERIFICATION	SIGNATURE OF REGULATORY AUTHORITY OFFICIAL ……	DATE SIGNED (DD/MM/YYYY) ……

INSTRUCTIONS

- This **Record of Crop Destruct** should be used to record inspection and trial termination activities and the fate of residual plant material remaining on the trial site.
- The **Record of Crop Destruct** should be retained by the **Trial Manager** and made available to **Inspectors** upon request.
- The accidental release of a GM plant and in case of any corrective action taken shall be immediately documented in a Record of corrective Action. The Original Record shall be retained by the Trial Manager, and copies shall immediately be submitted by facsimile to Regulatory Agency and the Authorised Party.

3.3.7 Record of detasseling/bagging

TRIAL MANAGER			**TRIAL SITE**	
LAST NAME	FIRST NAME	MI	SITE LOCATION CODE	
COMPANY/ORGANIZATION/INSTITUTION	DEPARTMENT/SECTION		TRIAL SIZE(MXM)	No. OF TRIALS AT THIS SITE
POSTAL ADDRESS			LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE	
			DISTANCE TO NEAREST GENETICALLY MODIFIED CROP FIELD (M)	DISTANCE TO NEAREST COMMERCIAL CROP OF ANY KIND (M)
TELEPHONE	FACSIMILE	E-MAIL	IS THE ISOLATION DISTANCE UNDER THE MANAGER'S CONTROL? □ YES □ NO	

GENETICALLY MODIFIED PLANTS UNDER TRIAL

REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DATE PLANTED (DD/MM/YY)	REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DATE PLANTED (DD/MM/YY)

DATA SHEET FOR RECORDING INSPECTIONS AND DETASSELING OR BAGGING

DATE INSPECTED (DD/MM/YY)	GROWTH STATE OF TRIAL PLANTS	DETASSELING PERFORMED □ YES □ NO □COMPLETE	BAGGING PERFORMED □ YES □ NO □COMPLETE	POLLEN SHED OBSERVED □ YES □ NO	INSPECTOR'S SIGNATURE
ADDITIONAL COMMENTS AND OBSERVATIONS					
DATE INSPECTED (DD/MM/YY)	GROWTH STATE OF TRIAL PLANTS	DETASSELING PERFORMED □ YES □ NO □COMPLETE	BAGGING PERFORMED □ YES □ NO □COMPLETE	POLLEN SHED OBSERVED □ YES □ NO	INSPECTOR'S SIGNATURE
ADDITIONAL COMMENTS AND OBSERVATIONS					

FATE OF PLANT MATERIAL

DESCRIBE HOW REMOVED PLANT MATERIAL WAS REMOVED
□ DRY HEAT □ STEAM HEAT □ BURNING □ DEEP BURIAL □ CHEMICAL TREATMENT
□ CRUSHING □ OTHER (detail below)

ADDITIONAL COMMENTS AND OBSERVATIONS

TRIAL MANAGER VERIFICATION	SIGNATURE OF TRIAL MANAGER	DATE SIGNED (DD/MM/YYYY)
THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	…… BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.	

INSTRUCTIONS

- Prior to inflorescence emergence, the trial site should be inspected at a survey determined by Regulatory Authority. Following inflorescence emergence and until **ALL** plants in the trial have been detasseled or bagged, trials should be inspected daily.
- This Record of **Detasseling/Bagging** should be used to record inspection and detasseling or bagging activities. Inspections should be carried out by the **Trial Manager** or a person designated by the **Trial Manager**.
- This record of detasseling/bagging should be retained by the **Trial Manager** and made available to **Regulatory Authority Inspectors** (RA) upon request.
- Growth stages of the trial plants are recorded based on the **Growth Stage Key** supplied with the Standard Operating Proceduress (SOPs)

3.3.8 Report forms for Post Harvest Inspection

TRIAL MANAGER			**TRIAL SITE**	
LAST NAME	FIRST NAME	MI	SITE LOCATION CODE	
COMPANY/ORGANIZATION/INSTITUTION		DEPARTMENT/SECTION	TRIAL SIZE	No. OF TRIALS AT THIS SITE
POSTAL ADDRESS		LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE AREA UNDER POST-HARVEST RESTRICTIONS ☐ **TRIAL AREA ONLY** ☐ **ISOLATION ZONE**		
TELEPHONE	FACSIMILE / E-MAIL	ISOLATION DISTANCE (M)	POST-HARVEST YEAR ☐ 1 ☐ 2 ☐ 3	

GENETICALLY MODIFIED PLANTS PREVIOUSLY AT THE TRIAL SITE					
REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DATE PLANTED (DD/MM/YY)	REFERENCE CODE/EVENT NAME	CFT PERMIT/NOTIFICATION No.	DATE PLANTED (DD/MM/YY)

DATA SHEET FOR RECORDING INSPECTIONS FOR THE PRESENCE OF PROHIBITED PLANTS					
DATE INSPECTED (DD/MM/YY)	PROHIBITED PLANTS PRESENT ☐ YES ☐ NO	GROWTH STAGE OF ANY PROHIBITED PLANTS	METHODS OF DESTRUCTION OF ANY PROHIBITED PLANT MATERIAL	ADDITIONAL COMMENTS AND OBSERVTIONS	INSPECTOR'S SIGNATURE
	☐ YES ☐ NO				
	☐ YES ☐ NO				

ADDITIONAL COMENTS AND OBSERVATIONS

TRIAL MANAGER VERIFICATION		
THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	SIGNATURE OF TRIAL MANAGER …… BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.	DATE SIGNED (DD/MM/YYYY)

INSTRUCTIONS

- Trial sites should be inspected for the presence of prohibited plants species (e.g. Gossypium hirsutum, G. barbadense, G. tomentosum). The period of post-harvest restriction begins on the date of termination of the trial, which is normally the harvest date.
- The **Record of Post-harvest Inspection** should be retained by the **Trial Manager** in the **Compliance Document Binder** and made available to **Regulatory Authority Inspectors** (RA) upon request.
- Upon completion, a copy of the signed **Record of Pos-harvest inspection** should be forwarded to the Authorised Party and to **RA**

3.3.9 Report forms for Corrective action

<table>
<tr><td colspan="4">TRIAL MANAGER</td><td colspan="3">TRIAL SITE</td></tr>
<tr><td>LAST NAME</td><td>FIRST NAME</td><td>MI</td><td colspan="4">SITE LOCATION CODE</td></tr>
<tr><td colspan="2">COMPANY/ORGANIZATION/n INSTITUTION</td><td>DEPARTMENT/SECTION</td><td colspan="2">TRIAL SIZE(MXM)</td><td>No. OF TRIALS AT THIS SITE</td></tr>
<tr><td colspan="3" rowspan="2">POSTAL ADDRESS</td><td colspan="4">LEGAL OR DESCRIPTIVE LAND LOCATION OF TRIAL SITE</td></tr>
<tr><td colspan="2">DISTANCE TO NEAREST GENETICALLY MODIFIEDCROP FIELD (M)</td><td colspan="2">DISTANCE TO NEAREST COMMERCIAL CROP OF ANY KIND (M)</td></tr>
<tr><td>TELEPHONE</td><td>FACSIMILE</td><td>E-MAIL</td><td colspan="4">IS THE ISOLATION DISTANCE UNDER THE MANAGER’S CONTROL? □ YES □ NO</td></tr>
<tr><td colspan="7">ACTIVITY REQUIRING CORRECTIVE ACTION</td></tr>
<tr><td colspan="3">INDICATE THE CATEGORY OF ACTIVITY REQUIRING CORRECTIVE ACTION AND THEN COMPLETE THE RELAVANT INFORMATION REQUIREMENTS UNDER TRANSPORTATION AND STORAGE OR TRIAL SITE

□ TRANSPORT □ STORAGE □ PLANTING
□ MONITORING □ HARVESTING □ OTHER

IF OTHER, DESCRIBE BELOW</td><td colspan="4">METHOD OF REPRODUCTIVE ISOLATION

□ SPARTIAL ISOLATION □ DETASSELING
□ TEMPORAL ISOLATION □ GUARD ROWS
IDENTIFICATION OF COMPLIANCE ISSUE

CHECK ALL THAT APPLY

□ UNAUTHORIZED SHIPMENT

□ PRIMARY SHIPPING CONTAINER BREACHED

□ ACCIDENTAL RELEASE DURING TRANSPORT

□ ACCIDENTAL RELEASE DURINGSTORAGE

□ BREACH OF SPARTIAL ISOLATION

□ FAILURE OF DETASSELING

□ ARTICLE LOST DURING SHIPMENT

□ RECORD OF TRANSPORT MISSING

□ RECEIVED AT WRONG DESTINATION

□ BREACH OF GUARD ROW ISOLATION

□ OTHER, BELOW

DETAILS OF COMPLIANCE ISSUE</td></tr>
<tr><td colspan="7">TRANSPORT AND STORAGE</td></tr>
<tr><td colspan="3">SHIPMENT No. ITEM No.</td><td colspan="4"></td></tr>
<tr><td colspan="3">FACILITY NAME</td><td colspan="4">STORAGE LOCATION IDENTIFIER</td></tr>
</table>

BUILDING NAME	ROOM NUMBER OR DESCRIPTION
ADDRESS (IF DIFFERENT FROM ABOVE)	

IDENTIFICATION OF AFFECTED ARTICLES

CFT PERMIT/NOTIFICATION No.	PLANT SPECIES	APPROX. AMOUNT OF AFFECTED MATERIAL (KGs)	FORM OF MATERIAL □ SEED □ BUDWOOD/SHOOTS □ TRANSPLANTS □ TUBERS □ WHOLE PLANTS

DESCRIPTION OF CORRECTIVE ACTION TAKEN

CHECK ALL THAT APPLY
□ DESTRUCTION OF ARTICLE □ RECOVERYOF SPILLED MATERIAL □ IMPOSE POST HARVEST RESTRICTIONS
□ ROGUING OF PROHIBITED PLANTS □ DETASSELING OF TRIAL PLANTS □ IMPOSITION OF SPARTIAL ISOLATION ZONE
□ DESTRUCTION OF NEIGHBOURING CROP □ DESTRUCTION OF TRIAL □ OTHER, BELOW

DETAILS OF CORRECTIVE ACTION TAKEN

TRIAL MANAGER VERIFICATION

THIS ACTIVITY HAS BEEN CARRIED OUT TO MEET CFTD PERFORMANCE STANDARDS AND/OR SPECIFIC PERMIT CONDITIONS FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED PLANTS AND PLANT PRODUCTS IN TANZANIA	SIGNATURE OF TRIAL MANAGER …… …… BY MY SIGNATURE, ABOVE, I ATTEST THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.	DATE SIGNED (DD/MM/YYYY) …… …...

THIS SECTION TO BE COMPLETED BY THE AUTHORISED PARTY

COMMUNICATION WITH REGULATORY AUTHORITY

NAME OF OFFICIAL FIRST CONTACTED	DEPARTMENT OR OFFICE	TELEPHONE	FACSIMILE	E-MAIL

SUMMARISE COMMUNICATION OUTCOMES, INCLUDING AGREED OPTIONS FOR RISK MITIGATION. ITEMIZE ALL COMMUNICATIONS, RECORDING DATE AND INDIVIDUALS INVOLVED ATTACH ANY WRITEN CORRESPONDANCE OR TRANSCRIPTS OF ORAL COMMUNICATIONS.

INSTRUCTIONS

- The Record **of Corrective Action** is used to document all corrective actions taken to mitigate or solve a situation involving the accidental release of a **Genetically modified** plant during transport and/or storage or any **breach of reproductive isolation** during the field testing of **GMOs.**
- A copy of this Record of Corrective Action, together with any other relevant records (e.g., Record of Transport, Storage Inspection, Spartial Isolation, Detasseling, Temporal Isolation, Harvest, etc.), shall be retained by the Trial Manager, and copies shall immediately be submitted by facsimile to RA and Authorized party. Also the Authorized party shall immediately notify RA Orally, and confirm such in writing within 24 hours.

3.3.10 Flower bud remove weekly Report

FLOWER BUD REMOVAL WEEKLY REPORT					
Trial: Site:					
Authorization Code Number:					
INSTRUCTIONS: **Summarize results of flower bud removal each (time), starting (time) after planting in soil, or earlier if branching is observed. Dispose of all flower buds by [method]. Answer/Y/N except a indicated.**					
Week of (Dates)	Number of inspections this interim	Flower Buds Present?	All Flower Buds Removed Prior to pollen production?	Flower Buds disposed of in on – Site Disposal Pit?	Verified By (Initials)
Checked for Accuracy and Completeness by Trial Manager Signature: Date:					

3.3.11 Report forms for volunteer monitoring

VOLUNTEER MONITORING				
Trial:		Site:		
Authorization Code Number:				
INSTRUCTIONS **Inspect the trial site for volunteers each [time period], starting one month after harvest. Identify and destroy any volunteer [crop] and not the method. Continue monitoring until the end of the post-harvest interval, xxx months after harvest.**				
Inspection Date (Day/Month/Year)	Volunteers Present?	If Present, What Growth Stage?	Volunteers Destroyed? Method of Destruction.	Verified By (Initials)
Example: 14 july 2006	Yes	Seedlings	Yes - Cultivation	SM
Checked for Accuracy and Completeness by Trial Manager **Name and Signature:** **Date:**				

3.3.12 Report forms for Interim report

INTERIM REPORT FOR CONFINED FIELD TRIAL	
Trial Site:	Location:
Permit Numbers:	Authorized Party:
Reported By/Title:	Phone/Fax:
Planting Date(s):	Harvest Date(s)
Attach a complete report summarizing observations, methods of observation data and analysis of experimental results, and any unanticipated effects observe provide an Executive Summary of the report in the space below (attach addition) pages if needed.	
P1 Name and Signature:	Date:
Date Submitted:	
REQUIRED ATTACHMENTS • Experiment Results and Conclusions	

3.3.13 Report forms for Trial progress report

TRIAL PROGRESS REPORT FOR CONFINED FIELD TRIAL	
Trial Site:	Location:
Permit Number(s)	Authorized Party:
Trial Manager:	Phone/Fax:
Planting Date(s):	
Date Flowering Began:	Date Flowering Ended:
REPRODUCTIVE ISOLATION AND CONFINEMENT	
List measures taken to assure reproductive isolation and confinement:	
Comments:	
Unless otherwise noted, check Yes or No in the appropriate box.	Yes No
Were all measures for reproductive isolation carried out according to requirements?	
If no, describe:	
Was any breach of reproductive isolation noted during flowering?	
If yes, describe:	
If yes, was an Incident Report filed?	
Comments:	
Inspector Signature:	Date:
Date Submitted:	

ANNEX 1. APPLICATION FORM FOR A CONFINED FIELD TRIAL IN TANZANIA[1]

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

☐ CBI COPY
☐ CBI DELETED
☐ NO CBI

General Instructions

This application form consists of eight parts which must be completed for **each individual genetically modified plant species** proposed for environmental release in a confined field trial in Tanzania.

All sections of this application must be completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Submit 5 copies of the application for use by the Tanzanian regulatory bodies in both hard and soft forms by regular mail or courier delivery.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Provide additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

Conduct a public notification in accordance to biosafety regulations of Tanzania.

The appropriate fee as stipulated in the biosafety regulations must accompany the application. Please note that the Vice president's office does not accept cash.

Applications must be received by National Biosafety Focal Pont (NBFP) at the address shown below **at least 180 days in advance** of any proposed introduction.

Permanent Secretary
Vice President's Office
P.O. Box 5380
Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

The authorizing party shall acknolewdge receipt within two weeks.

[1] This application form is specific for plants released in the environment. Guidelines for release of other GMO applications including animal, microbes and fish will be prepared later by NBFP.

Part 1: Applicant/administrative Information

1.1 Applicant

Name of Principal Investigator (PI):

Postal address:

Physical Address:

Telephone:

Mobile phone:

Fax:

E-mail:

Attach:
- Current CV
- Name of and Contact of three referees

1.2 Name and address of Institution

Name of institution:

Postal address:

Physical Address:
- Street:
- District:
- Town/City:

Telephone:

Fax:

E-mail:

Website:

1.3 Title and purpose of the proposed experiment

Title: Purpose:

1.4 Previous Applications or Approvals

Provide information on the status of this crop and trait, including pending, approved, or denied applications for field trials and commercial releases here or in other jurisdictions. Indicate also if this is a new application, supplementary or a renewal

1.5 Proposed Location and Size of Trial:

Provide name, address, email, phone, and facsimile of the Trial Manager as well as GPS information or description of the exact location and size of the trial site (attach sketch map)

1.6 Proposed Duration of Trial:

Expected starting date: Expected termination date:

Part 2: Plant Information

2.1. Unmodified Plant Information

This section describes the characteristics of the unmodified plant as it relates to confinement. Important information pertains to the plant's reproductive mechanisms and its ability to escape, establish, and persist in the environment into which it is being introduced.

2.1.1 Plant Species

Common name:……..... Scientific name:.....……

2.1.2 Centre(s) of Origin

What is the centre of origin of the unmodified plant?

2.1.3 Centre(s) of genetic diversity

What is the centre of genetic diversity of the unmodified plant?

2.1.4 Reproductive Mechanism of the Plant

Describe the reproductive biology of the plant. This information may be obtained from Organization for Economic Co-Operation and Development (OECD) biology consensus documents or similar sources, and should include relevant information on: inter- and intra-specific breeding; pollen production, dispersal, and viability; seed production and dispersal; seed dormancy; capacity for vegetative reproduction, availability of free living populations of the plant species in Tanzania

2.1.4 Tendency to:

a) Weediness

Is the unmodified plant regarded by agricultural experts as a weed in Tanzania or elsewhere? If so, are control methods available that may be used to effectively limit the dispersal and establishment of the unmodified plant?

NOTE: The information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this application.

b) Pest

Is the unmodified plant regarded by agricultural experts as a pest in Tanzania or elsewhere? If so, are control methods available that may be used to effectively limit the dispersal and establishment of the unmodified plant?

NOTE: The information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this application.

2.1.5 Toxicity and Allergenicity

Is the plant species known to be a source of substances that are toxic or allergenic to humans or animals? If yes, identify the substances and levels that induce toxicity or allergenicity and the affected species

2.1.6 Allelopathy

Is the plant species known to be allelopathic? If yes, give details

2.2. Modified Plant Information

This section is intended to provide information on known or intended effects of the genetic modification or introduced trait that may effect confinement measures employed in the confined trial.

2.2.1 Describe the Intended Phenotypic Changes (traits) to the Plant

2.2.2 Intended Reproductive Effects

Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes effect strategies for confinement?

2.2.3 What is the source of the gene?

• Is the source of the gene likely to affect the safe conduct of a confined field trial? If yes, how? • Describe any known or intended introduction of infectious agents, plant, animal or human pathogens or allergens or toxins.

2.2.4 Changes in Toxicity or Plant Composition

Describe any changes to toxicity, allergenicity, or significant changes in composition intended by the genetic modification.

2.2.5 Describe

a) The Features of the Genetic Construct Include coding sequences, promoters, enhancers, termination, selection markers and polydenylation signal sequences. Attach a genetic map and describe the method of modification in an annex. *b) The vector(s) used*

2.2.6 Stable Integration of the Inserted DNA

• Indicate the site of Integration of the Introduced DNA • Indicate how stable integration of the DNA was demonstrated

2.2.7 Expression Products of the Introduced Gene(s)

Provide information for each protein product of the introduced gene(s) - maximum level of expression in the edible portions of the plant, whether the protein known to be allergenic or toxic to humans or animals

Part 3: Impact Assessments

• Environmental Risk Assessment (ERA) *Provide ERA report*

Part 4: Experimental Description

Describe the purpose of the field trial, anticipated planting and harvesting dates, the experimental design and data to be collected, including anticipated use of pesticides, fertilizers and any agro-chemicals. Include a description of the habitat at the site, and any organisms of conservation concern that may be in the general area.

Part 5: Genetic Confinement

This section describes the measures to be taken to ensure confinement of the genetically modified plants. It is based on knowledge of the unmodified crop and the intended genetic modification.

5.1 Provide a map showing the location of the trial site, surrounding fields, and relevant geographic features such as streams or waterways

5.2 Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting in viable seeds? If yes, what are the species

5.3 Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial site

Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and/or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology

5.4 Describe measures in place to control plant volunteers after termination of the experiment

Describe the crops to be allowed following the confined trial, duration of monitoring for volunteers, frequency of monitoring, methods of destruction and disposal of any identified volunteers, and any other measures needed to ensure that the trial plants do not persist on the trial site

Part 6: Material Confinement

This section describes the mechanisms by which trial personnel will maintain control of the genetically modified plant material, so that it is not mixed with non-modified plant material, does not escape into the environment, and is not eaten by humans or livestock.

6.1 Packaging

Describe how the genetically modified plant material will be packaged and labelled for transport to the trial site and measures for cleaning and/or disposing of the packaging material. Note that the chain of custody documentation is required for all genetically modified material being transported

6.2 Harvesting, Transport, and Storage

Describe how the plant material will be harvested, including plans for any material to be retained, and how that material will be stored and/or transported

6.3 Disposal and Clean-Up

Describe how surplus planting material will be disposed of at the trial site, how any equipment used during planting or other farm operations will be cleaned, and how harvested materials crop residues and waste water will be disposed

6.4 Site Security

Describe measures in place to ensure security of the trial site to prevent incursion by humans or animals. Measures may include fencing, security patrols, lockable gates, etc

Part 7: Records, Personnel, and Planning

7.1 Records and Documentation

Describe measures in place to ensure adequate documentation of all confinement measures and data requirements as described herein

7.2 Contact Details of Site Manager

Name of Site Manager: Postal address: Physical Address: Telephone: Mobile phone: Fax: E-mail: Attach current CV

7.3 Personnel

Briefly describe competence of the PI, Site Manager and key project personnel. Describe measures in place to ensure that trial personnel will have appropriate education, experience, and training to adequately perform assigned duties for confinement and technical requirements of the trial

7.4 Contingency Plans

Describe planned response to the loss of control or accidental release of genetically modified plant material, including notification of authorities and the Authorized Party, recovery and disposal of plant material, and any other measures to be taken to mitigate any potential adverse effects

Part 8: Declaration and Signatures

I hereby declare and certify that the information in this application is complete and accurate to the best of my knowledge and belief.

Principal Investigator

Name:

Signature: Date:

Project Supervisor (Institution Head)

Name:

Signature Date: