A HANDBOOK FOR THE CONDUCT OF CONFINED FIELD TRIALS OF BANANAS

EDITED BY
Arthur Makara
&
Jeff Stein

IN COMPLIANCE WITH THE STANDARD OPERATING PROCEDURES FOR CONDUCT OF CONFINED FIELD TRIALS IN UGANDA AS PREPARED BY THE UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Uganda National Council for Science and Technology

Uganda National Council for Science and Technology
P.O. Box 6884, Kampala, Uganda
Email:uncst@starcom.co.ug
www.uncst.go.ug

Program for Biosafety Systems
International Food Policy Research Institute
2033 K Street, NW
Washington, DC 20006-1002
USA
www.ifpri.org/pbs/pbs.asp

Donald Danforth Plant Science Center
975 N. Warson Road
St. Louis, Missouri 63132
USA
www.danforthcenter.org

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7 REPORTING AND INSPECTIONS

Regular reporting at the time of planting, during progress of the trial, after trial termination, and after post-harvest monitoring for this trial will be required including in the cases of any incidences such as breakage of the fencing, or intrusion, as per the SOPs for Reporting and that for Incidents in the Trial Managers' Handbook.

Inspections shall be carried out by the Biosafety Inspectors, or NBC members, or their agents. Inspection may occur at any time during the trial period. However, at the beginning of the trial when the site has been prepared, the Authorised Party must notify the NBC secretariat to inspect the field. Similarly, at the time of planting the plantlets in the field trial, the NBC must be notified as well as at the termination of the trial when the plants will be devitalised with glyphosate. The NBC reserves the right to arrange impromptu inspections on the trial during its progress. Details on inspection can be found in the manual for Biosafety Inspection, which is essentially a guiding document for Biosafety Inspectors and the NBC to audit the implementers of the trial so as to ensure compliance with the set guidelines and conditions of approval of the trial.

Foreword

This handbook is a product of the Biosafety Office at the Uganda National Council for Science and Technology and the Regulatory Approval Strategies component of the Program for Biosafety Systems at the Donald Danforth Plant Science Center. It has been produced with the realisation of the need to provide specific guidance in the manner of which confined field trials of genetically modified bananas will be conducted in Uganda. This handbook is not intended to supplant the Standard Operating Procedures for Confinement as provided in the Trial Managers' Handbook either in part or as a whole in the conduct of banana confined field trials. Rather, the specific guidance provided in this handbook is designed to augment the provisions of the Standard Operating Procedures found in the Trial Managers' Handbook and those of the Confined Field Trial Guidelines for Uganda.

It is our wish and hope that all the staff that will be engaged in the conduct of Confined Field Trials in Uganda will find this manual useful. It will also act as a reference point to the implementation of confined field trials of genetically modified bananas in other countries beyond Uganda.

Director
Regulatory Approval Strategies
Donald Danforth Plant Science Center

Executive Secretary
Uganda National Council for Science and Technology

1 INTRODUCTION

This handbook provides specific elaboration of compliance procedures required for conducting the Confined Field Trial of genetically modified (GM) bananas in Uganda. This handbook has been developed to guide all the workers involved with the trial to ensure maximum biological and physical confinement. As provided for by the Confined Field Trial (CFT) Guidelines, *genetic confinement* refers to measures put in place to ensure that propagative materials do not escape from a field trial into the surrounding environment where they can potentially germinate and grow into mature plants, whereas *material confinement* refers to measures put in place to ensure that the crop in confinement is not consumed by humans, livestock or animals. This handbook is therefore meant to facilitate the principal investigator, the trial manager, and their staff participating in conducting the trial to follow the CFT guidelines and the Standard Operating Procedures for the Conduct of Confined Field Trials as detailed in the Trial Managers' Handbook.

6 POST-TRIAL MONITORING

Post-harvest monitoring will be conducted at least once during a 3-month interval for a period of one year (minimum of 4 inspections during the 12-month period). Any volunteers that emerge during this period will be uprooted and buried in the disposal pit, and activities recorded in the Volunteer Monitoring Form provided in this Handbook. Access to the trial site will continue to be restricted during the post-harvest monitoring period. Only non-compatible plants can be grown at the trial site (see Section 7.0, Table 3 of the Trial Managers' Handbook).

FORM 3: VOLUNTEER MONITORING

Trial Site Identification:

Authorization Code Number(s):

Instructions: Inspect the trial site for volunteers once every three months, beginning one month after harvest. Identify and destroy any volunteer banana plants and note the method. Continue monitoring until the end of the post-harvest interval, 12 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

Signature: **Date:**

5 TRIAL TERMINATION

5.1 Devitalisation of Plants

Plant devitalisation will be accomplished by glyphosate injection. All banana bunches must remain on the mother plants at the time of devitalisation. If yield data is to be collected from some of the experimental plants, and the banana bunches cut off for this purpose, the Trial Manager must keep proper record of sampling and if possible, bunch data should be taken within the perimeter of the trial site. This activity is to be recorded in the Crop Destruction Form (see Appendix 6.4.1 of the Trial Managers' Handbook). Following data collection, the banana bunches must be chopped and deposited into the disposal pit burnt and covered with a layer of soil. Plant tissue cannot be removed from the trial site unless the procedure described in this Handbook in Section 4.2 "Tissue Removal" is followed.

5.2 Plant Removal and Disposition

The plants devitalised by glyphosate must be allowed sufficient time to desiccate after which they will be cut down, placed into the disposal pit, if possible burnt, and/then covered with a minimum layer of 12 inches of soil. The corms will also be up-rooted, chopped and deposited into the disposal pit in a similar manner. Activities shall be recorded in the Crop Destruction Form provided in the Trial Managers' Handbook in Section 6.4.1.

2 PLANTLET TRANSPORTATION AND PRE-PLANTING ACTIVITIES

2.1 Packaging

The banana plantlets shall be packed according to the SOP for Packaging Materials (see Section 3.1.1 of the Trial Managers' Handbook). There should be a primary container (which in this instance is the culture tubes in which reside the plantlets). These tubes shall be packaged within a secondary container such as plastic tubes. Finally, these secondary containers are to be packaged within a metallic casing or other sturdy box. Each of the containers (primary, secondary and tertiary) must be labelled according to the SOP for Transport and Storage (see Section 3.1.2 of the Trial Managers' Handbook).

The final disposition of the packaging materials (e.g., primary, secondary, and tertiary containers) must be conducted in accordance to the SOP for Retention, Disposal or Re-use of Packaging Materials (see Sections 3.1.3 and 3.1.4 of the Trial Managers' Handbook).

2.2 Receipt and Transportation

Receipt and transportation of the plantlets must be conducted in accordance to the SOP for Receipt and Shipment (see Section 3.2 of the Trial Managers' Handbook), and activities recorded in an improved version of the Shipment & Storage Form below (for original, see Section 3.4.2 of the Trial Managers' Handbook). In addition, the transportation has to be accompanied by a Biosafety Inspector or a member of the NBC up to the Kawanda Research Station as per the terms and conditions of approval of the application by the National Biosafety Committee.

Arrangements should be made to transport the containers harbouring the plant material from the airport directly into the containment facility (greenhouse). Transportation of the plant material should be in an enclosed vehicle (e.g., car or van rather than a pickup truck) in order to ensure that no plant material spills from the vehicle during transport. Further, upon unloading of the containers at the containment facility, the vehicle should be thoroughly inspected to ensure that no plant material has remained in the vehicle.

2.3 Temporary Storage

In some instances, the plant material must be placed in temporary storage prior to placement into the approved greenhouse containment facility. This temporary storage area must be limited to a specifically designated area within the Biotechnology Laboratory at Kawanda Agricultural Research Institute and storage should not exceed 48 hours. Please refer to the specific guidance on secure storage as described in the SOP for Storage (see Section 3.3 of the Trial Managers' Handbook) and complete all of the information in the Labelling and Plant Material Storage Record (next page).

The Trial Manager must accompany anyone who wishes to enter the trial site (including visitors and workers) and his/her details must be recorded in a logbook to be kept by the Security Guard on behalf of the Trial Manager. The logbook must detail the individual's name, address, date, reason of entry, time in and time out and he/she must sign on exit. The role of the security guard is therefore not to admit or accompany visitors or workers into the site but rather to ensure that there is no unauthorised entry into and no tampering within the site.

4.2 Tissue Removal

During the management of the trial, suckers, leaves and sheaths that are pruned from the experimental plants shall be chopped and deposited into the disposal pit, immediately covered with a thin layer of soil, and these activities recorded in the Crop Destruction Form (see Appendix 6.4.1 of the Trial Managers' Handbook). No material shall be taken from the trial site unless the following process is satisfactorily completed: (1) the individual wishing to move plant material submits a written request to the Trial Manager, describing the name(s) of all individual(s) who will be responsible for said material, the purpose of the proposed activity, description of the said plant material (e.g., leaf, stem), and amount being moved, description of packaging and transportation activities, and proposed final destination of said material; (2) the NBC secretariat will be notified of the proposed activity by the Trial Manager; and (3) upon receipt of the secretariat approval, the Trial Manager will issue a written authorisation to the individual requesting such plant movement. A complete record of this activity (as described above) will be kept on file at the trial site.

Male flower bud development shall be monitored at a twice-a-week frequency during the reproductive development phase of the plant's growth, and all developing buds shall be removed and the tissue deposited into the disposal pit. A record of male bud removal shall be maintained in the Flower Bud Removal Weekly Report Forms provided in Section 4.4.2, page 22, of the Trial Managers' Handbook (version 1.0; March 2006).

Form (see Section 4.4.2 of the Trial Managers' Handbook). The Trial Manager must ensure that all plantlets are accounted for at the time of transfer of the acclimatised plants to the field trial site, and this activity recorded in the appropriate section of the Planting Form. In the event that there is need to retain any plants, justification for this should be reported to the NBC secretariat by the Trial Manager, and this activity is to be recorded in the Planting Form. In the event that excess plant material must be disposed of, this should be performed in accordance with the SOP for Disposal of Excess Material (see Section 4.1.5 of the Trial Managers' Handbook). These activities are to be recorded in the Crop Destruction Form (see Appendix 6.4.1 of the Trial Managers' Handbook).

3.2 Equipment

The equipment used in establishment of the trial must be cleaned of all plant debris in accordance with the SOP for Equipment (see Section 4.14 of the Trial Managers' Handbook), and activities recorded in the Crop Destruction Form (see Appendix 6.4.1 of the Trial Managers' Handbook). In addition, if such equipment is to be used during trial management, it should be kept in the store on the trial site.

4 TRIAL MANAGEMENT

4.1 Site Security

The trial site, together with the greenhouse, will be fenced off with a wire mesh fencing at a minimum height of 3 meters. The biosafety guidelines require that a 24-hour security guard be deployed at the entrance of the trial site. The security room should be located outside the field trial fence, adjacent to the main gate. The trial store should be located inside but along the fence with two doors, one on the outer and the other on the inner side to ensure that one does not have to enter the trial site only to pick something from the store. Keys to the main entrance to the trial site, those of the greenhouse and those of the inner door of the store must be kept by the Trial Manager.

FORM 1: SHIPMENT AND STORAGE

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

SHIPPING INFORMATION

	Shipped		Received			Shipped		Received	
Line	Amount	By	Amount	By	Line	Amount	By	Amount	By
Total									

Packaging:		Shipper Initial/sign	
Conveyance:		Shipper Initial/sign	
Depart [origin]:	Date:	Time:	
Arrive [destination]:	Date:	Time:	

RECEIVING 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 after receipt:	
Receiver Signature:	Date:

FORM 2: LABELLING & PLANT MATERIAL STORAGE RECORD			
Shipment Origination:			
Location of Storage Facility:		**Item:**	
Your Name:	**Date of Shipment Arrival:**		
PACKAGING AND LABELLING			
Upon receipt of a shipment of genetically modified plant material at your location, please record the following information, in addition to filling the shipment and storage form in the Trial Managers' Handbook (3.4.2)		**YES**	**NO**
Was the plant material enclosed within a primary, secondary, and tertiary container?			
Were any of the containers structurally compromised such that loss of plant material may have occurred during shipment?			
Was the packaging material inspected for plant material prior to disposal?			
If the packaging has not been retained, has authorization for disposal been documented?			
How was the packaging material disposed of?			
Comments:			
SHIPMENT DOCUMENTATION [SEE AND COMPLETE FORM 3.4.2 OF CFT TRIAL MANAGERS' HANDBOOK]			
Are all Shipping Forms adequately completed, signed and dated?			
Are copies of all shipping documents available in the trial file?			
Comments:			
STORAGE AREA			
Is the storage area restricted to authorized personnel only?			
Is the area sign-posted according to requirements?			
Are GM plant materials kept separate from non-GM materials?			
Are GM plant materials clearly identified?			
Is a current inventory list available for GM materials in the storage area?			
Comments:			
Your Signature:		**Date:**	
Trial Manager Signature:		**Date:**	

2.4 Transfer to Greenhouse

In the event that the plantlets were stored in a temporary confinement facility, a record will be made in order to verify that all plants housed in this temporary storage location have been transferred to the greenhouse. This record will include such elements as: (1) date of transfer to the greenhouse; (2) number of plants transferred to the greenhouse; and (3) number of plants remaining in the temporary storage facility. In the event that some of the plants are withheld from transfer to the greenhouse, written justification for keeping those plants in the temporary facility must be provided by the Trial Manager, and an estimate of the duration for the storage must be stated in the appropriate section of the Shipment and Storage form. This information will be reported to the NBC secretariat at UNCST by the Trial Manager.

In the event that the plants are transferred from one size of pots to another, the used pots must be incinerated within the perimeter of the trial site fence, and this activity recorded in the appropriate section of the Planting Form (see Section 4.4.2 of the Trial Managers' Handbook). Since the greenhouse is located within the perimeter fence surrounding the trial site, and since it has a lockable gate, it is the responsibility of the Trial Manager to ensure that all the plants that were reconceived are weaned and those that have been weaned remain in the greenhouse till the time of planting into the trial site.

3 TRIAL ESTABLISHMENT

3.1 Planting

The NBC secretariat must be notified of the anticipated date and time of planting at least 72 hours prior to the initiation of planting activities. Planting-related activities must be recorded in the Planting Form provided in Section 4.4.2 of the Trial Managers' Handbook.

Upon transfer of the acclimatised plants from the greenhouse to the trial site, the used pots and any residual soil from the plants must be collected and incinerated on site, and this activity recorded in the appropriate section of the Planting