A Handbook for the

Conduct of Confined Field Trials of Transgenic Cotton in Uganda

The Uganda National Council for Science and Technology

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Photo Captions:
Front Page: Participant at the Cotton Confined Field Trial Managers' Training Workshop inspecting a field of non-GM cotton at the National Semi-Arid Resources Research Institute (NaSARRI).
Back Page: Some of the Participants at the Cotton Confined Field Trial Managers' Training Workshop at the National Semi-Arid Resources Research Institute (NaSARRI), Serere, Eastern Uganda in October 2008 in a field of non-GM cotton (fore-ground is Dr. Thomas Emeetai Areke, the Director of NaSARRI and PI for the GM Cotton CFT studies).

Foreword

Cotton is an important cash crop in Uganda that has been grown for nearly 100 years. The peak of production was realized in the early 1970s when about 500 thousand bales were produced annually. Unfortunately the crop suffered decline due to several factors including civil strife, production and marketing constraints. In spite of this set back, cotton is still a major cash crop for many farmers in Eastern, Northern and Western Uganda. Currently cotton is among the priority crops under the Government Strategic intervention on export commodities and the target is to produce one million bales annually. When achieved, this would increase the export earnings from the current US $ 40-50 millions to US $ 200 million and improve household incomes in the production areas. Achievement of the target however, requires alleviation of a number of production, processing and value-addition constraints. Biotechnology could solve some of the prominent production constraints of insect and weed pest management.

The main production challenge in the cotton sector is the scourge of pests such as bollworms, jassids and mites among others. Quite often several sprays of insecticides have to be applied to cotton fields to minimize losses from pests making cotton the crop with the highest use of pesticides worldwide. In Uganda most farmers cannot even afford to spray as recommended, so heavy losses are incurred. Biotechnology can offer a solution to the pest infestation, in particular the bollworms, if Bt varieties are adopted. Bt cotton was developed with a gene from the soil bacterium *Bacillus thuringiensis* (Bt) that produces proteins that can kill several lepidopteran pests such as bollworms.

Bt cotton is now widely cultivated in several countries in the world including China, India, USA, South Africa and Mexico and currently constitutes 43% of the cotton cultivated in the world. This Bt cotton is also under research in several countries including our neighbouring Kenya. The cotton sub-sector has also already identified Herbicide Tolerant cotton in addition to Bt cotton as products that should be tested,

evaluated and researched for possible adoption in Uganda.

The introduction of transgenic crops in Uganda such as transformed cotton has been a subject of debate for several years. A regulatory system has been developed by the Uganda National Council of Science and Technology (UNCST), the Competent Authority designated by Government, and with support from UNEP-GEF.

The UNCST and other stakeholder institutions have organized sensitization workshops, training courses, study tours and consultative meetings to build consensus and make sure decision makers are well informed about the subject. A number of Ugandans have also benefited from formal training and built research facilities, all this amounting to adequate capacity to handle various types of biotechnology research.

A key factor to consider when introducing new crops or crop varieties such as transgenic cotton, is safety of the product to the environment and human health. Fortunately in the case of cotton there is a history of safe use. The social-economic factors are also critical but these may vary with country and production environments. Hence before any new cotton variety (whether transgenic or not) developed from within or outside the country, enters the production system, it has to be evaluated for adaptation and efficacy. On this basis, the National Agricultural Research Organisation (NARO) made an application to the National Biosafety Committee to conduct a Confined Field Trial (CFT) of Bt cotton in the country. This trial would help NARO to come up with recommendations on the commodity tested and design future strategies on transgenic cotton research and development. This application was approved, hence the need to train trial managers on the requirements for implementing a Confined Field Trial (CFT).

This manual therefore presents us with the detailed procedure to follow when conducting cotton CFTs of regulated genetically modified cotton. The manual should be used in conjunction with the Confined Field Trial Guidelines and the Trial Manager's Handbook that details the Standard Operating Procedures for CFTs.

This manual is intended for use by those responsible for implementing Cotton CFTs and should support safe and responsible design, management, and reporting on the cotton CFT in compliance with the scientific and regulatory principles and guidelines.

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Contents

Executive Summary

This handbook is meant to give a straight-forward description of the regulatory procedures for confined field testing of transgenic crops in Uganda with specific emphasis on cotton.

The introductory chapter includes background information on the regulation of biotechnology, the purpose of confined field trials, the biology of cotton and transgenic cotton. The core of the handbook is primarily a description of the standard operating procedures with specific elaboration of compliance procedures required for conducting the Confined Field Trial of GM cotton in Uganda.

Considering the specific biology of cotton as a crop and also the specific requirements of the National Biosafety Committee (NBC) in the approved conduct of confined field trials (CFTs) of cotton 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 Guidelines, genetic confinement refers to measures put in place to ensure that introduced genes do not escape from a field trial into the surrounding environment through pollen flow or through propagative material that can potentially grow into mature plants and reproduce, and material confinement refers to measures put in place to ensure that all GM plant tissue is maintained within the confines of the approved field trial site or storage facility and does not enter the food or feed supply.

This handbook is therefore meant to facilitate the principal investigator, the trial manager, and their staff working on the trial to follow the CFT Guidelines, the Standard Operating Procedures (SOPs) elaborated in the Trial Managers' Handbook as well as other terms and conditions of approval issued by the NBC in the conduct of confined field trials of transgenic cotton.

It should however be noted that this handbook is not a substitute for any of the said Government regulatory documents but rather a means to help in ease of compliance. For this reason it must be used in conjunction with the Trial Managers' Handbook (Version 1, March 2006) that contains the Standard Operating Procedures. The interpretation of the said documents solely remains the responsibility of the authorised research scientists or their agents.

Acknowledgments and Disclaimer

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This activity was conducted as a consultancy for the Program for Biosafety Systems (PBS) Project, under the Uganda Associate Award Project. The Project National Executing Agency is the Uganda National Council for Science and Technology (UNCST).

This handbook is not in any way meant to substitute the already existing Guidelines and Regulations for Genetically Modified crops in Uganda but is rather a supportive document that gives specific guidance on conduct of CFT of genetically modified cotton. This handbook is not meant to be used alone but rather in reference to the Trial Manager's Handbook that contains Standard Operating Procedures for Confined Field Trials in Uganda.

Acronyms

Bt	*Bacillus thuringiensis*
CFT	Confined Field Trial
GM	Genetic Modification/Genetically Modified
HT	Herbicide Tolerant
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
NBC	National Biosafety Committee
PBS	Program for Biosafety Systems
PI	Principal Investigator
rDNA	Recombinant Deoxyribonucleic Acid
SOP	Standard Operating Procedure
TMH	Trial Manager's Handbook
UNCST	Uganda National Council for Science and Technology

Glossary

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

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

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

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

Confined Field Trial (CFT): A field trial of GM plants not approved for general release, in which measures for reproductive isolation and material confinement are enforced, in order to restrict the experimental plant material and genes to the trial site.

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

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

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

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

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

Genetic Confinement: Measures put in place to ensure that introduced genes do not escape from a field trial into the surrounding environment through pollen flow or through propagative material that can potentially grow into mature plants and reproduce

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

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

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

Material Confinement: Measures taken to ensure that all GM plant tissue is materially maintained within the confines of the approved field trial site or storage facility and does not enter the food or feed supply

NBC: The National Biosafety Committee, a committee within UNCST which discharges the responsibilities of UNCST in regulation of GMOs.

PI: Principal Investigator, the lead scientist in a confined field research study. He/she may himself/herself be the Authorised Party if he/she is the applicant or he/she may be a designated agent or lead scientific collaborator of the Authorised Party.

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

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

Propagative Plant Material: Plant material such as seeds or cuttings

capable of establishing and surviving in the natural environment without human intervention.

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

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

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

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

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

UNCST: The Uganda National Council for Science and Technology, which is the body responsible for regulating the testing and release of GMOs in Uganda.

Volunteers: Progeny arising from the GM crop in a confined field trial site after the trial has been terminated

Section Guide

Section 1:

Introduction

1.1 Regulation of Biotechnology

The advent of biotechnology has come with many promises and also many challenges, including concerns about the safety of its products both to human health and to the environment. This is the principle reason biotechnology has come to close scrutiny compared to other technologies developed in the agriculture sector. Regulation of biotechnology therefore is meant to ensure that the technology is safe by ensuring environmental and food safety. It was because of these concerns that an international protocol for regulation of biotechnology was negotiated. This is known as the Cartagena Protocol on Biosafety, which entered into force on 11th September 2003, 90 days after receiving the 50th instrument of ratification, including Uganda's. Through standard practices therefore, methods of regulating biotechnology at the national level have been developed as a result of domestication of the Cartagena Protocol on Biosafety. Each of the signatory countries to the protocol is obliged to put in place regulatory regimes and institutional frameworks for regulation of modern biotechnology. In Uganda, there is a National Competent Authority, the Uganda National Council for Science and Technology which has a National Biosafety Committee (NBC) that reviews and approves all applications involving rDNA technology. In each of the institutions conducting GMO research, there is an Institutional Biosafety Committee (IBC) that works with the scientists to ensure that what they are doing is safe, and the IBC submits regular reports to the NBC. There is also a system, implemented by the NBC, for compliance inspection and monitoring of trials and facilities in place for conducting modern biotechnology research in Uganda. All these are aimed at ensuring that biotechnology is conducted in a safe manner and once new products or varieties are released, they are safe for both human consumption and the environment in which they are growing.

1.2 What Are Confined Field Trials?

Confined Field Trials (CFTs) are restricted and controlled field

experiments that are used when conducting studies on transgenic crops beyond the greenhouse in the field. They are normally small scale (usually not more than 2 hectares), performed under strict terms that ensure that the experimental material is restricted from moving beyond the boundaries of the study area and are similar to field trials of conventional crops only that the CFTs have added restrictions. CFTs are essential for technology evaluations in modern biotechnology research and development. The crop which had been first developed in the laboratory and typically evaluated in the green house needs to be tested under real field conditions in a natural or local environment. Field trials can enable breeding experiments to be conducted in case there is a need to introgress the genes from experimental plants into the local varieties under experimental conditions, help in identification of superior lines for variety selection, and can help when scaling up seed production for use in larger-scale experimentation of trial releases. Confined field trials are critical for the accumulation of scientific information necessary for informing regulatory decisions by the NBC and competent authorities as well as assisting scientists in deciding on the next course of action for scaling up their research.

Confined field trials are hinged on three major pillars: controlling the material from escaping from the trial in order to prevent consumption by humans or livestock, prevent mixing with non-GM material, and prevent persistence in the environment. The methods used vary based on the biology of the crop. There are specified methods for handling, storing, and transporting plant material. The crop is isolated in the field from non-GM material of the same species for specified distances, which vary from crop to crop. These measures are aimed at preventing gene flow from the test plants in the field to sexually compatible plants in the environment. Persistence of test plants in the field is also prevented by removing volunteers after the trial has been terminated. The later exercise requires regular monitoring of the field for a period that varies from crop to crop but one year in the case of cotton. In Uganda, at present, every confined trial must be fenced off and guarded by a security guard. All of these measures contribute to achieving both genetic and material isolation and confinement.

1.3 Brief Biology of Cotton

Gossypium hirsutum, the cotton species cultivated in Uganda, belongs to the family Malvaceae that consist of several weedy and a few cultivated species. The cotton plant usually is considered an annual, although it is a perennial in some parts of the world. The woody, herbaceous plant has a long tap root and attains a height of 2 to 5 feet or taller under favourable conditions. Cotton grows best with high temperatures and adequate soil moisture and fertility. Flowering usually begins about 7 to 11 weeks after planting. Determinate varieties stop growing after boll development. The flower bud or square usually is discernible 3 to 4 weeks before the flower opens. Many of the buds, squares, flowers or young bolls drop off naturally. This is called shedding. As a result, it is estimated that only 35 to 40 percent of the squares produce mature bolls under normal conditions. The most critical time for developing fruit is 3 to 10 days after pollination. The period between flowering and opening of mature bolls is 6 to 8 weeks, depending on growing conditions.

Fruit of the cotton plant is the enlarged 3- to 5-loculed ovary commonly referred to as a cotton boll. Mature bolls vary in size and shape depending on the variety and environmental conditions but usually are 1-1/2 to 2 inches in diameter. Bolls set during the first 3 weeks of fruiting usually are the largest and contain the highest quality fibre. The cotton plant can adapt to different environmental stresses. In a severe drought, the plant may be only 6 inches high but still capable of producing several bolls. A plant of the same variety grown under adequate moisture or irrigation may be 5 feet in height and produce 40 to 50 bolls. A population of 30,000 to 65,000 plants per acre is the optimum range for maximum yields. Once bolls are 12 days old or older, they usually will not shed unless the plant suffers severe stress (temperature, moisture, insects or disease).

Average Growth and Fruiting of the Cotton Plant	
Planting to emergence	4 to 10 days
Emergence to first true leaf	8 days
Emergence to second true leaf	9 days
Second true leaf to pinhead square (seventh node)	18 to 21 days
Pinhead square to matchhead square	9 to 10 days
Matchhead square to first one-third grown square	3 to 6 days
First one-third grown square to first white bloom	12 to 16 days
First white bloom to first open bolls	40 to 60 days
Harvest bolls set first 4 weeks of blooming	96%
Percent blooms that make bolls	35 to 40 %

1.4 Pests of Cotton

Key pests are serious, perennially occurring, persistent pests that dominate control practices because their populations may cause severe economic damage in the absence of control. The following are key pests of cotton, and they vary in their severity and prominence based on a variety of factors.

As the cotton grows, different insect pests become important. In early stages, cotton aphids move into the crop, feeding on the nitrogen-rich, new young leaves. A small bug, the Lygus attacks the youngest leaves and the young fruit buds of the crop. When buds, flowers and bolls appear, a number of different caterpillars (bollworms) feed on them. The bollworms are the single most damaging pests of cotton in Uganda, causing yield loss of sometimes up to 100%. Further on during the development of the crop, cotton stainers appear and pierce the bolls causing fungi to discolour the lint. Each of these pests has its own biology and conventional control measures. However, the advent of modern biotechnology has helped scientists to develop resistant

varieties to some of the major pests. The Bt cotton to be tried in Uganda has for instance been improved to resist the cotton bollworm pests.

1.5 Weeds as a Cotton Production Constraint

Weeds are a major cause of low cotton yields in Uganda. They are particularly damaging in the first 2-4 weeks after cotton seedlings have emerged, as during this period, the crop grows slowly while the weeds grow very fast. Weeds cost farmers money in the following ways: they take up and use fertiliser which is applied to benefit the crop; it costs as much money to apply insecticides to a weed infested crop as to a weeded one but yields will be less hence more loss on investment; weeds reduce yield and hence loss of revenue. Weed control is therefore very important but use of the hand hoe on large fields of cotton renders the task labourious and money consuming. Scientists therefore have developed transgenic herbicide tolerant cotton that is also going to be tested in Uganda under Confined Field Trials. This renders the cotton crop tolerant to herbicide Roundup™ and when the cotton field is sprayed with the herbicide, only the weeds die whereas the cotton remains normal. The farmer spraying the crop therefore does not have to be worried that the crop is going to be destroyed by the herbicide. This will therefore save time and money in the long run while helping to improve yields.

1.6 What is Transgenic Cotton?

A transgenic crop is one that contains a gene or genes which have been introduced into its genome using methods of modern biotechnology. The inserted gene(s) may be derived from an unrelated plant or a completely different organism, such as a bacterium. 'Bt' and 'transgenic' have been sometimes used synonymously but are not the same. A Bt crop is a transgenic crop that specifically has a gene inserted into it from a soil micro-organism known as *Bacillus thuringiensis* (Bt), which confers resistance to certain insect pests. In the case of cotton, we therefore have what is known as Bt cotton that contains genes from *Bacillus thuringiensis* for resistance to the bollworm pest. On the other hand, transgenic cotton where the genes have been derived from sources other than *B. thuringiensis* are not referred to as Bt cotton, as is the case of herbicide tolerant (HT) transgenic cotton. Bt cotton therefore

is resistant to the bollworm pest, whereas HT cotton is tolerant to a particular herbicide, and when a field of this kind of cotton is sprayed with this herbicide, it kills only the weeds but not the cotton. Both are transgenic cotton varieties.

From this explanation, it is clear that Bt cotton is genetically engineered to resist bollworm pests, but the question is of what advantage is this method compared to spraying the crop with conventional pesticides? Before we proceed, we may need to take note that when purified forms of Bt are used as organic pesticide sprays, they are sprayed on the crops and they exert their action when the bollworm pest eats up the Bt, which binds to receptors in the insect gut, ruptures the gut walls, hence causing the death of the pest. The receptors are specific to the insect, and are not found in other organisms, which makes the Bt active only against the specific insects. The challenge here is that Bt sprays will not last for long on the leaves and are inactivated within a few hours. However, when the Bt gene responsible for killing the insect pest is incorporated within the plant itself by genetic engineering, the insect toxin is produced within the plant cells and remains active for a considerably longer period of time. Whenever the bollworm consumes a portion of the plant in which Bt protein is being expressed, the toxin will be available to rupture its gut walls resulting in the insect's death. This mode of insect control can reduce the need for conventional pesticide spray hence potentially saving costs, time, soil residue, and impacts on other organisms such as pollinators or health of the farmer.

Section 2:

Standard Operating Procedures

2.1 Transportation of GM Material and Pre-planting activities

2.1.1 Packaging

The cotton seeds shall be packed according to the SOP for Packaging using standard materials to prevent any accidental release. Packaging shall also ensure that tampering can be detected easily. The seed will be packaged directly into fully labelled double cotton bags (primary containers) which will be contained in a single large cotton bag (secondary container), which will be packed into a fibre board drum appropriately labelled with the contents of the drum (tertiary container).

The disposal or recycling of the packaging materials (e.g., primary, secondary, and tertiary containers) must be conducted in accordance to the SOP for Disposal or Re-use of Packaging Materials where by the primary containers have to be incinerated and disposed off. The secondary and tertiary containers, if they have to be re-used or used for other purposes must be cleaned thoroughly and inspected to be devoid of any seed or GM material.

2.1.2 Receipt and Transportation

Receipt and transportation of the seeds must be conducted in accordance to the SOP for Receipt and Shipment in the Trial Managers' Handbook, and activities recorded in an improved version of the Shipment & Receiving Form provided in the Trial Manager's Handbook (TMH). Transportation of the plant material should be in an enclosed vehicle (e.g., car or van rather than on a pickup truck) in order to minimise any possibility of spillage of the seeds. In addition, the transportation must be accompanied by a Biosafety Inspector or a member of the NBC to the Research Station as per the terms and conditions of approval of the application by the NBC (See Appendix).

2.1.3 Temporary storage

Arrangements should be made to transport the seeds to a store room at the research station where the trial(s) is to be conducted. Entry into the storeroom where the seeds are stored should be restricted to the Principal Investigator and Trial Manager, or personnel authorized by them, during the entire period of temporary storage into this store of the seeds before they are sown, or of any unused seeds after planting. The cabinet in which the seeds shall be stored should be lockable and clearly marked with a label that helps identify such a cabinet, e.g., Do Not Open: Contains GM Materials for Research Purposes Only. In addition, the storeroom in which the materials are stored should be lockable and appropriately labelled, especially if the seeds are not stored in a lockable cabinet with in this storeroom. The packaged seed inside the cabinet should be clearly marked as "GM Materials". Please refer to the specific guidance on secure storage as described in the SOP for Storage given in the TMH.

Seeds should be transported from the temporary storage to the field for planting in multiple packaging and with care to ensure that no spillage of seed happens. Since transportation takes place on the day of planting, a Biosafety Inspector should be present when this transfer is conducted.

2.2 Trial Establishment

2.2.1 Planting

The NBC secretariat must be notified of the anticipated date and time of planting at least 3 working days prior to the initiation of planting activities so that inspection can be arranged. Planting-related activities must be recorded in the Planting Form provided in the TMH.

Upon transfer of the seed containers to the trial site and emptying the containers of the seeds, the used containers and/or any associated materials should be incinerated on site if possible, or thoroughly inspected and cleared of any remaining seed, if it is not a material that can be incinerated or may have to be used for other

purposes. This activity should be recorded in the appropriate section of the Planting Form provided in the TMH. The Trial Manager must ensure that all seeds are accounted for at all times. Unplanted seeds should be destroyed on site by incineration. In the event that there is a need to retain some seeds, justification for doing this should be reported to the NBC Secretariat before planting day and to the inspector on site, stating the amount of seeds to be retained, where they will be stored, how they will be stored, and for how long, as well as a clear explanation of the reason they have to be stored, by the Trial Manager. 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 and the activity should be recorded in the Crop Destruction Form provided in the TMH.

The trial must be planted at a separation distance of at least 200 meters away from any conventional cotton to minimise any possibility of cross contamination of pollen. However, within the trial itself, the GM cotton will be surrounded by (1) a fallow of 1 m and (2) a 12 m perimeter of non-transgenic cotton. This non-transgenic cotton should be treated as transgenic cotton throughout the trial including final destruction and disposal.

2.2.2 Equipment

The equipment used in establishment of the trial must be cleaned by appropriate means in accordance with the SOP for Equipment and activities recorded in the Crop Destruction Form given in the TMH. In addition, if such equipment is to be used during trial management, it should be kept in the store on the trial site.

2.3 Trial Management

2.3.1 Site security

The entire perimeter of the trial site will be fenced off with a wire mesh fencing of not less than 2.5 meters high. It is a specific

requirement of the Ugandan biosafety guidelines that a 24 Hour Security Guard be deployed at the entrance of the trial site. The security room should therefore be located outside the field trial fence, just adjacent to the main gate. The trial store should be located inside the trial site but near its entrance. Keys to the main entrance to the trial site and those of the store must be kept by the Trial Manager.

The Trial Manager must accompany whoever enters the trial (including visitors and workers) and the details of the visitors must be recorded in a logbook to be kept by the Security Guard on behalf of the Trial Manager. This logbook is also inspected by biosafety inspectors during routine trial inspections. The logbook must detail the visitors name, address, date, reason of entry, time in and time out and he/she must sign on exit. In case of a group of visitors, each must register individually. The role of the security guard is not to admit or accompany visitors or workers into the site but rather to ensure that there is no unauthorised entry into the site including tampering with it.

2.3.2 Plant Tissue removal

During the management of the trial, any plant material pruned or weeded from the site must be disposed in the disposal pit and either covered with a thin layer of soil or burned and such activities should be recorded in the Crop Destruction Form. No plant material should at any time be taken out of the trial site unless the following process is satisfactorily completed: (1) the Trial Manager submits a written request to the NBC Secretariat, describing the names of all individuals who will be responsible for said material, the purpose for the removal, nature of packaging and transportation, destination of said material, a description of the said material (e.g., plant parts such as leaves, and amount being moved), and must first obtain written authorisation from the NBC Secretariat before the material is moved out of the trial site. This therefore means that such communications should be made in time to ensure that the NBC secretariat responds. Whatever is removed and the purpose of removal will be recorded and kept on file at the site also giving the

names and addresses of the persons that are handling it outside confinement.

Flowering will take place normally, cotton bolls will be formed and allowed to mature and open. Both GM and non-GM cotton will be harvested, but ginning will be done on the CFT site. This therefore implies that a large enough store should be put in place to store the seed cotton before ginning. It will be ensured that all the seeds collected after the ginning exercise will as much as possible be collected and incinerated accordingly to minimise emergence of volunteers. The ginning exercise must be inspected by a Biosafety Inspector. A record of this exercise must be recorded in the Trial Harvest and Crop Destruction Form.

2.4 Trial termination

2.4.1 Devitalisation of plants

Devitalisation of the plants will be accomplished by uprooting the cotton plants and burning them in the incineration pit. A combustion agent such as paraffin should be used to accelerate the burning. Care should be taken to ensure that no plant materials leave the confined field trial area. This activity shall be recorded in the Crop Destruction Form.

2.4.2 Post-trial Monitoring

Post harvest monitoring will be conducted at monthly intervals for two seasons (one year). Any volunteers that emerge during this period will be uprooted and disposed into the incineration pit and burnt accordingly and such activities recorded in the Volunteer Monitoring Form provided in the TMH. Access to the trial site will continue to be restricted during the post-harvest monitoring period. Only non-compatible crops, beans etc., can be grown on the trial site, if there is urgent need to re-use the plot.

2.5 Reporting

Regular reporting at 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 incidents and reporting in the Trial Managers' Handbook. Records for incidents and other reports must be recorded in the appropriate forms provided in the Trial Managers' Handbook.

2.6 Inspections

Inspections shall be carried out by the Biosafety Inspectors or NBC members or their agents and should be expected any time during the trial. Regular inspections in the case of cotton shall be conducted at least once every month. However, at the beginning of the trial when the site has been prepared, the Authorised Party (Principal Investigator) will have to notify the NBC Secretariat to inspect the field before planting. Similarly at the time of planting the trial and at the time of termination of the trial, the NBC Secretariat has to be notified in advance of three days so that inspection can be arranged. The NBC reserves the right to arrange impromptu inspections of the trial during its progress. Other details on Inspection can be found in the Manual for Biosafety Inspection.

2.7 Contingency Planning

Good contingency planning for serious incidents, however unlikely, is the key to successful amelioration of any exposure or environmental impact from these incidents. The Authorized Party shall establish a contingency plan in accordance with the requirements of the SOPs stipulated in the TMH, and shall provide training for all trial personnel on the SOPs or other authorized contingency plan(s).

Section 3:

Communicating about the CFT

The scientists working on modern biotechnology have to invest reasonable amounts of resources in communication and public engagement because the technology is still surrounded with controversy. Strategic networks and partnerships have to be built right from the conceptualization of the research and it is these partnerships that will authenticate and give a wider publicity to the research work that is being conducted by the scientists.

There is a strong need to involve organizations that have some linkages or interface with the eventual consumer of the technology because the consumers have to be assured of the safety of the technology being developed. In the case of confined field trials, the scientists must engage the public early enough and at all times.

They should make the public clearly understand the purpose of the trial and the need for confinement, what the eventual benefits of the trial are, what they should expect from the trial itself and after the trial, and what will come next.

There has to be in-built resources within the research budgets for public engagement and communication and bringing different stakeholders to witness what is being done on field trial sites. This is what has been termed as 'seeing believing' visits and during such visits, the scientists and regulators must work closely and with civil society organizations to allay any fears about the trial and the technology being tested.

The collaborating institutions should work together according to a well-laid down communication strategy developed by all stakeholders and implementation of this strategy should start well ahead of implementation of the trial.

The communication channels and modes as well as champions, should be clearly spelled out at strategy development level. If this is not done,

the trial might be conducted successfully but amidst public speculation of what is being done by the scientists. This has serious implications if the technology being tested is successful and the scientists need to take it to the next level, because they may face resistance from the consumers and the general public, including government itself, if there has not been effective communication.

References

1. **Nyiira Z.M., Kakule J.F. and Mugoya C.F., 2000:** Uganda Biosafety Framework, Uganda National Council for Science and Technology

2. **Stein J., and Makara A.M. (Eds.), 2006:** A Handbook for Conduct of Confined Field Trials of Genetically Modified Bananas in Uganda. PBS/UNCST Joint Publication.

3. **UNCST, 2006:** Confined Field Trial Guidelines for Uganda: For Field Experiments with Genetically Modified Plants

4. **UNCST, 2006:** Trial Manager's Handbook: Procedures and Forms for Field Experiments with Genetically Engineered Crops (Version 1, March 2006).

Appendix

Some of the terms and conditions of approval of the GM Cotton applications (Application Ref. No. GM/ CFT/001-2/07 decision No: 1/2008)

1. The permit issued shall be copied to the Department of Crop Protection in the Ministry of Agriculture, Animal Industry and Fisheries to facilitate importation of the seeds for the trial

2. A Phytosanitary certificate must be obtained from the Phytosanitary department of MAAIF at the time of importing the seeds into the country

3. The consignment must be inspected at the point of entry by the Phytosanitary inspectors and the Inspector must accompany your planting material/seeds to the store at the research institute.

4. NARO/NaSARRI will facilitate the inspector to carry out this inspection task

5. After preparation of the trial site, the Principal Investigator (Authorised Party) will inform the NBC of the anticipated date of planting.

6. At the time of planting, in the middle of the trial and at harvest inspections by the Biosafety Inspectors and NBC Members will be done. It is the responsibility of the Authorised Party to inform the secretariat about the impending activity so that the inspection can be arranged but at your cost.

7. The NBC and the Inspectorate reserve the right to make an impromptu inspection (giving you prior notice or not).

8. The details of terms conducting the trial, shipping and storage, material and genetic confinement, termination of the trial, post-harvest monitoring, incidents, data collection for regulatory purposes as well as record keeping has been provided to you in the Trial Manager's Handbook Version 1.0 March 2006. It is your responsibility as the Authorised Party to ensure that all the guidelines that are of relevance to your crop and study are strictly followed. These are what the inspectors shall be auditing during inspection.

9. Standard Operating Procedures and Confined Field Trial Guidelines must be followed and any non-compliance with these SOPs and Guidelines as well as other conditions of approval (3.0 and 4.0) will constitute commitment of an offence and the authorised party will be liable to penalties as the NBC and/or a Competent Court may determine according to the laws of Uganda as well as relevant international laws, where applicable.

Notes:

For More information contact:
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