



**Report of the training of field managers for the cotton
Confined Field Trial**

21st to 22nd October 2008

NaSARRI, Serere, Soroti

Edited by

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Acronyms

Bt	<i>Bacillus thuringiensis</i>
CFT	Confined Field Trial
GM	Genetically Modified
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
NARO	National Agricultural Research Organisation
NaSARRI	National Semi Arid Resources Research Institute
PBS	Program for Biosafety systems
SCIFODE	Science Foundation for Livelihoods and Development
SOPs	Standard Operating Procedures

Background

Uganda's population is now estimated at 30 million, with 89% of these living in rural areas and dependant on agriculture for their livelihoods. Agriculture has been the mainstay of the economy, in addition to ensuring food security that is important for development. Food and cash crops grown account for over 70% of the agricultural GDP of the country. The main traditional cash crops have been cotton, coffee and tea and these have provided income for millions of farmers in rural areas. Coffee and tea are perennials primarily cultivated in Central, southern and western parts of Uganda where as cotton is an annual grown mostly in Eastern and Northern parts of the country.

The cotton industry in Uganda has evolved tremendously since 1931 when the crop was introduced into the country. In the past decade, the country implemented reforms in the sector to improve the industry targeting exports of 1 million bales a year from the current 350,000 bales. The main 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 minimise losses from pests making cotton the crop with the highest use of pesticides worldwide. This prompted scientists to develop more sustainable and less destructive methods of controlling cotton pests. Biotechnological tools were employed and cotton was successfully transformed with a gene from the soil bacterium *Bacillus thuringiensis* that produces proteins that kill several lepidopteran pests such as bollworms. This genetically modified cotton, or Bt cotton as its known, 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. Bt cotton has registered successes in all countries where it is cultivated with insecticide use reducing to 2-5 sprays per season from 8-12 sprays and yield benefits reaching 30% in some instances. The crop is therefore expected to improve yields and subsequently incomes of farmers in Uganda when adopted.

Bt cotton however has not undergone testing to ascertain the efficacy of the technology under the local conditions. The National Biosafety Committee of Uganda recently approved an application from the National Agricultural Research Organisation (NARO) to conduct a Confined Field Trial (CFT) of Bt cotton in the country. The researchers

now await a seed import permit from the Ministry of Agriculture to begin the trials to be conducted at Serere in Eastern Uganda and Mobuku in Western Uganda. Confined field trials of genetically modified (GM) crops are conducted under stringent guidelines that are followed by all people involved in the field experimentation. There is therefore need to train all persons involved in such trials on best practices to follow in management of CFTs.

The National Semi Arid Resources Research Institute (NaSARRI) of NARO, and the Program for Biosafety Systems (PBS) organised a training workshop to develop capacity of scientists and researchers involved in the CFT study. The training was conducted on 21 -22nd October 2008 at NaSARRI in Serere, Soroti District in Eastern Uganda. The training drew participants that included researchers, trial managers, inspectors, regulators, local council representatives and journalists (Appendix 2). Topical issues such as technical challenges, risks, standard operating procedures and communication strategies were covered by experienced resource persons from Uganda and USA. A team from Malawi, that included scientists and regulators, also attended the training.

Objectives of the training

- To develop capacity of personnel involved in managing cotton Confined Field Trials

Below is a summary of the proceedings from the training that was chaired by Dr. Theresa Sengooba.

Activity 1: Welcome remarks

The Coordinator, Program for Biosafety Systems - East Africa, Dr. Theresa Sengooba in her remarks:

- Welcomed the members to the training.
- Outlined the existing Biosafety regulatory framework and confined field trial (CFT) procedures in the country

- Emphasised the importance of the agricultural sector in Africa and encouraged members to have a sound thought about biotechnology as a way of transforming the sector and probably that could start with the cotton industry.

Activity 2: Opening remarks

The Director NaSARRI, Dr. T. E. E. Areke in his remarks:

- Welcomed participants to NaSARRI and gave an overview of NARO and its research activities
- Described the mandate of NaSARRI that included research on crops such as finger millet, sorghum, oil crops (groundnuts, sesame, sunflower), fibre crops (cotton), legumes (beans) and pasture
- Mentioned that Uganda needs to embrace biotechnology as a way to contribute to improved farm incomes and better livelihood
- Outlined the purpose of the training; training field managers on confined field trial procedures.

Activity 3: Presentations

Presentation 1: *Why regulate biotechnology?* Karen Hokanson, PBS-USA

In her introduction, Karen told participants that while Uganda had its first cotton CFT approved for planting Malawi was preparing to handle their first application for CFT of transgenic cotton. She then described Biotechnology in a broad sense, and the need to regulate it. Karen said biotechnology needs to be regulated for several reasons including; it's a new technology, there is no history of safe use, to assure food and environmental safety, it's a legal requirement under Cartagena Protocol on Biosafety, public perception, and then to facilitate technology development and transfer.

She further noted that the Cartagena Protocol on Biosafety influences how individual countries are developing their regulatory framework but does not replace national or domestic regulatory frameworks. Karen also elaborated on biotechnology versus conventional breeding tools, the process of genetic transformation including the two

main approaches used (agrobacterium mediated and gene gun approach) and regeneration procedures.

Karen explained that biotechnology being new implies need for regulation. In this regard, she mentioned fear of unknown, desire or demand for certainty, resistance to change, memories of bad experience and reluctance to make trade offs as arguments for the regulation of biotech.

In conclusion, Karen presented the status of GM crops in the world, showing the countries with highest acreage of GM crops.

Questions and comments on presentation 1

Participant

Is Bt crop organic? Does it become inorganic once transformed?

Response from Karen

Organic farming is more to do with individual approach or description but GMOs are not classified as organic by the promoters of organic agriculture.

Participant

What are the trade issues regarding Bt?

Response

GMO issues are either production or market oriented but the trade issues are the main concerns of promoters of organic farming. Communication is necessary to fill the gaps in public knowledge.

Presentation 2: Material and Genetic confinement for CFTs; Jeff Stein, PBS - USA

Jeff mentioned that CFTs are necessary and critical steps to commercialising GMO's. He further stated that CFTs require appropriate planning to ensure safe CFT implementation.

Jeff then described CFTs as 'field experiments to evaluate the performance of GM plants'. He elaborated that CFTs are usually small scale and are performed under

stringent terms and conditions that confine the experimental material but they are essentially similar to field experiments done for conventional breeding except that they are confined. Jeff then mentioned that CFTs, are essential for technical assessment.

On the need for CFTs, Jeff listed the following reasons; test the GM plants under real field conditions, test the value of the trait in local environment, breed biotech trait into local varieties, enable selection of superior lines for development, scale up product material prior to commercial approval, and generate safety data needed for subsequent risk assessment and approval.

Jeff then described the process of development and deployment of GM crops that he summarized as:

Lab → green house → CFT → full safety assessment → commercial release

He further mentioned the difference between confinement and containment by describing ‘contained’ as the situation when materials are enclosed within a container such as a lab or greenhouse and ‘confined’ as that situation when the gene and plant material are kept in a specific area. Both concepts however are to do with research or experimentation. Confinement minimises risk by lowering exposure.

Jeff also told participants that the pillars of confinement include: control the plant material, prevent gene flow and prevent persistence. He then mentioned that certain terms and conditions have to be met during confinement. Material confinement is achieved through proper handling of seed, trial site, equipment and post harvest land-use restriction. Genetic confinement is achieved through distance (spatial) isolation to reduce chances of natural cross pollination with other materials in the vicinity of the trial. Good material confinement also helps minimise gene flow. Jeff added that tracking is an important aspect in confinement and this has to continue after harvest.

In his conclusion, Jeff said field trials are essential for development of GM crops adapted for local environment and confined field trials can be performed safely and routinely by enforcing proper material and genetic confinement measures.

Questions and comments on presentation 2

Participant

How does one control gene flow to weeds?

Response

Sexually compatible relatives need to be considered to prevent gene flow and this is done through means such as temporary isolation (e.g. Detassling prior to flowering).

Participant

What is the effectiveness of isolation distances?

Response

Jeff replied by stating that isolation distance is meant to minimise gene flow effects and to reduce risk but not to provide 100% isolation.

Participant

What is the cleaning mechanism used for personnel in experiments?

What is done to limit insect pollination such as by bees?

Response

Personnel working in CFTs are regulated through restriction of movement of the workforce itself, use of gear (separate/confined gear) between GMO fields and conventional field.

Insect pollination can be minimised by using GM pollen buffers/traps, and combined special isolatinos. Also, the fact that a CFT is a small experimental trial reduces the risk of gene flow.

Presentation 3: *Transgenic cotton*; Theresa Sengooba, PBS – East Africa

In her presentation, Theresa defined a transgenic crop as “Crop that contains a gene or genes which have been artificially inserted. The inserted gene(s) may come from an unrelated plant or from a completely different species”. Transgenic cotton has been modified primarily for two traits, insect resistance (Bt cotton) and herbicide tolerance.

She then elaborated on the discovery and use of toxins from *Bacillus thuringiensis* as insecticides and the subsequent incorporation of the Bt gene into cultivated crops including cotton, maize and eggplant.

Theresa also explained the advantages of Bt cotton such as reduction in damage by bollworms, reduced use of insecticides and less field scouting by farmers. The adoption of Bt cotton in the world was also presented. She further mentioned the use of herbicide tolerant cotton including its merits over conventional cotton.

Countries growing transgenic cotton were listed as USA, China, Mexico, India, Brazil, Argentina, Colombia, and South Africa while Egypt, Burkina-Faso and Kenya are conducting research on the crop.

On the need for transgenic cotton in Uganda, Theresa mentioned that there is an urgent need for Uganda to increase productivity hence the country should find out if transgenic cotton can offer a solution. Bt gene in an appropriate variety should contribute positively to increased cotton yields.

In conclusion, Theresa said there is need to understand the motives of anti-biotechnology activists who many times do not have data to back up their claims. Scientists need to communicate and inform the public accurately.

Presentation 4: *Biology of Cotton and Cotton pests in Uganda*; Thomas Areke, NaSARRI

In his presentation, Thomas explained that cotton is a unique crop as it provides natural fibre as well as edible oil and animal feed. Cotton (*Gossypium hirsutum*) was naturally a perennial crop but became annual after domestication. Cotton is a warm climate crop and requires about 750mm of water for proper growth. Taxonomically cotton belongs to the family *Malvaceae* of the order *Malvales*. *Gossypium hirsutum* is the most commonly cultivated species of the genus *Gossypium* but others includes *G. barbadense*, *G. arboretum* and *G. herbacium* although the genus includes about 50 species. Uganda cultivates only *G. hirsutum*, an allotetraploid ($2n = 52$).

Thomas further elaborated the biology of cotton. The cotton plant parts include nodes, branches (monopodial and sympodial), flowers, seeds, and roots. Branches occur in a spiral order on the stem with sympodial branches bearing fruits. The flower is a full one and flower formation start 4 to 5 weeks after planting. The crop is self fertilising although outcrossing may occur up to 10% due to insect activity. Wind pollination is not possible and insect pollination is controlled by chemical applications. Pollen dispersal is localised around pollen source and decreases significantly with distance. The cotton boll is formed immediately after fertilisation and matures in about 50 days. Bolls may have various shapes and weights depend on variety. Cotton seed results from fertilised ovule and produces the fibre for which cotton is grown. The seed is can remain viable for up to five years and contain 15 to 22% oil. The cotton plant has a tap root system that can grow up to 3m deep depending on growing conditions.

He then highlighted the constraints to cotton production in Uganda that include; insect pests, diseases, poor soil fertility, weeds, poor agronomic conditions. The most important cotton pests are; cotton boll worm (causing 40 to 100% yield loss), lygus bugs and cotton stainers. Important diseases cotton include bacterial blight and wilts.

Questions and comments on presentation 4

Participant

What is the current status of cotton varieties in Uganda?

Response from Tom

There are two variety classifications i.e. SATU – Serere Albar Type Uganda, that is more tolerant to drought and BPA –Bukalasa Pedigree Albar.

Participant

What are the production constraints in the country and how does one prevent against tendencies of minor pests to increase when major pests are defeated?

Response

Data is being collected on flora and fauna and there are entomologists in place to advise in case such situations arise.

Participant

How do the variety development, testing and seed systems operate in Uganda and how is the system managed?

Response

There is monitoring under the Cotton Development Organisation (CDO) and NaSARRI.

**Presentation 5: *Compliance to SOPs and Key elements of the Decision Document;*
Arthur M. Makara, SCIFODE**

Arthur introduced his presentation by describing the need for Standard Operating Procedures (SOPs). SOPs are required to prevent escape of novel genes from the trial site, prevent consumption of GM plant material by animals or humans and to prevent GM plants from escaping from confinement and establishing/persisting in the environment. In essence, SOPs help achieve genetic and material confinement of GM crops.

He further explained that different SOPs are required for packaging, shipment and storage of GM plant materials. All containers of GM plant material are required to be labelled clearly and properly sealed to avoid any chances of material finding way into the environment or food/feed. In the field, a number of measures are used to achieve genetic and material confinement. Arthur described the SOPs at field design, planting, plot labelling, crop growth, and sampling. Inspection should be conducted at all stages and that adequate security (24hr) should be at the trial site to limit entry of non-authorised persons and animals.

Arthur further mentioned that specific SOPs are set out for the termination phase of the CFT. At this stage, the principle investigator of the CFT has to notify the National Biosafety Committee before proceeding with the harvesting process. After harvest, monitoring is also conducted for a period that depends on the biology of the crop, for cotton the period is one year. Other SOPs are also provided for incidences and reporting.

A description of the composition and role of the NBC was also presented. Arthur detailed the current biosafety regulatory framework in the country that involves several stages, stakeholders and regulatory agencies. He further illustrated the interplay between stakeholders (public, farmers, UNCST, Institutional Biosafety Committees, the applicant, and the NBC).

On the decision making procedure, Arthur noted that several steps are taken before any application is granted. The applicant has to present his case before the NBC and a decision is taken by consensus. He then described the key elements of the decision document including reference number, communication of the decision, risk assessment procedure undertaken, and risk mitigation measures and conditions of approval.

Questions and comments on presentation 5

Participant

What is the period between application and approval?

Response from Arthur

Period between application and approval is 270 days, based on Cartagena Protocol, but the actual duration depends on the efficiency of the NBC and the time the applicant may take to respond the queries that may be raised during the review process.

Presentation 6: Cotton Confined Field Trials at Serere and Mobuku; Technical Challenges and Opportunities for Uganda. Simon Byabagambi, Makerere University

In his presentation, Simon explained the process of having a CFT approved. Initially, the applicant applies to the Institutional Biosafety Committee (IBC) and the IBC then sends the application to NBC. After approval, GM seed import permit is sought from the Ministry of Agriculture Animal Industry and Fisheries (MAAIF) (if the GM seed is to be imported).

A description of the structural requirements for a CFT including the location, design, construction, isolation distance and personnel was also presented. Incinerator, fence,

store room, guard house, and shower room are some of the structures that must be on a CFT site.

On the technical challenges involved, Simon said that the greatest challenge is the bureaucracy involved in the entire process from application to seed import. He said clearance by the NBC, UNCST and MAAIF often takes a lot of time. Another challenge he mentioned is the extensive material, structures and personnel required for a CFT.

In conclusion, Simoni highlighted the main opportunities for Uganda as capacity building, lessons in handling GM plants and availability of localised information on risk assessment, production, and general use of GM plants.

Presentation 7: *Genetically modified banana for resistance to Black Sigatoka disease; Experience with a confined field trial, David Talengera, NARLI*

David started his presentation by stating that banana is an important staple for millions of Uganda but faces several challenges from pests and diseases. The major pests he mentioned include weevils and nematodes while black sigatoka and banana bacterial wilt are the main diseases in the country. He then described the approaches employed in breeding for resistance to diseases including conventional and biotechnological methods. He also mentioned some achievements of banana breeding using biotechnology tools e.g. capacity building, development of cell suspension systems, development of banana transformation systems and protocols, and development of transgenic bananas.

He also elaborated the strategy used in developing black sigatoka resistant bananas. The plant defence mechanism was enhanced to restrict fungal growth, reduce disease development, and confer increased resistance using Chitinase genes *rcc2* and *rcg3* from rice to the banana cultivar Gros Michel (genotype AAA). The CFT was necessary because characteristic *Mycosphaerella fijiensis* infection and sporulation are not observed *in vitro* or in the greenhouse and would require field evaluation to observe correct black sigatoka disease development. The CFT objectives included determining the extent of transgene expression in the field, analysing the efficacy of transgenes for

Presentation 8: *Conducting a Confined Field Trial of a Genetically Modified Crop Plant: Compliance and Contingency Considerations*; Jeff Stein, PBS – USA

Jeff defined compliance as ‘*Strict adherence to the terms and conditions described in the approved permit to conduct the confined field trial*’. He then gave some examples of permit conditions such as sturdy packaging for seed shipment, controlled access to GM seed storage, ensuring sufficient spatial isolation from commercial plantings, adequate security to prevent encroachment by unauthorized personnel or animals, cleaning of planting equipment prior to exiting GM field plot, disposition of GM plant material at harvest, post-trial monitoring and volunteer destruction.

He further said that proper education of personnel on SOPs, roles and record keeping is necessary in achieving compliance. Adequate preparation on trial site and team is also important. Compliance monitoring at individual self and team levels as well as record keeping is also necessary.

On contingency planning, Jeff said there should a plan in-place to contend with possible compliance infractions, as unlikely as they may be. He gave examples of such incidences as spillage of planting material and intrusion of animals into the field. The goal of planning in this case would be to prevent further loss of GM material or to prevent GM material from being consumed by animals or humans or to prevent GM material from establishing and persisting in the environment.

Jeff concluded by mentioning possible measures to enforce in case there is breach e.g. notifying the project manager, stabilising the area, preventing consumption by human and livestock, and notifying regulatory authorities among others.

Presentation 9: *Communication about the CFT and best practices for managers*; Arthur M. Makara, SCIFODE

Arthur mentioned that communication is essential in building a long-term relationship with different categories of people and there is need to emphasise target outcomes of the study when communicating. Communication also helps to build public confidence on the safety of technologies developed. In the banana CFT, the trial manager is the

focal point in communicating with the media, Principal Investigator (PI), collaborators, regulators and the public in general.

The major challenge in communication is the anti-biotech campaigners and there is need to continuously engage them to demystify the technology. The media is yet another group that has to be attended to because media reports can change public perception. Scientists therefore have to develop the skills necessary to explain scientific work in simple terms that can be understood by lay persons. Effective communication should be made at every phase of the development process. Arhtur concluded by advising scientists to always be prepared to answer any questions that may addressed to them from time to time.

Appendix 1: Program for training of Cotton CFT field managers

Chairperson: Dr. Theresa Sengooba

Time	Presentation/Activity	Resource person
9:30-9:45am	<i>Welcome remarks</i>	Theresa Sengooba
9:45 - 10:00am	<i>Opening remarks and objectives of the training</i>	Tom Areke
10:00-10:20am	<i>Why regulate Biotechnology?</i>	Karen Hokanson
10:20-10:40am	<i>Material and Genetic confinement for CFTs</i>	Jeff Stein
10:40-11:00am	<i>Transgenic cotton</i>	Theresa Sengooba
11:00-11:15am	Coffee break	
11:15-11:45am	<i>Biology of Cotton and cotton pests in Uganda</i>	Tom Areke
11:45-12:30pm	<i>Compliance to Standard Operating Procedures and Key elements of the Decision Document</i>	Arthur Makara
12:30-1:00pm	<i>The Cotton CFT at Serere and Mubuku; Technical Challenges and Opportunities for Uganda</i>	Simon Byabagambi
1:00-1:45pm	<i>Experiences and Lessons learnt from the Banana Confined Field Trial</i>	David Talengera
1:45–2:45pm	Lunch break	
2:45-3:30pm	<i>Compliance and Contingency Planning</i>	Jeff Stein
3:30- 4:15pm	<i>Communication about the CFT and best practices for managers</i>	Arthur Makara
4:15 - 5:15pm	<i>Field visit to trial site</i>	Tom Areke
5:15-6:30pm	Coffee break/video	

NB: Discussions were conducted after each presentation

Appendix 2: List of participants

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Appendix 3: Photo gallery

