



Agricultural Biotechnology in Africa:

Stewardship Case Studies





Agricultural Biotechnology in Africa: Stewardship Case Studies

**Created as part of the 'Strengthening Capacity for
Safe Biotechnology Management
in Sub-Saharan Africa' (SABIMA) Project**

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Life cycle diagram: *Excellence Through Stewardship (ETS)*.

Photos— Left: *Tissue culture plantlets at National Agricultural Research Laboratories, Uganda*.
Right: *GM cassava confined field trial at National Crops Resource Research Institute (NaCRRI), Uganda* (Laura Johnson)

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Preface

The project on Strengthening Capacity for Safe Biotechnology Management in Sub-Saharan Africa (SABIMA) is a partnership between the Forum for Agriculture Research in Africa (FARA), a continent-wide agricultural research, technology dissemination and adoption advocacy and support agency, and the Syngenta Foundation for Sustainable Agriculture (SFSA), a global non-profit organization that supports smallholder agriculture for food security and poverty reduction. SFSA provided the financial and technical support to FARA to manage the project in sub-Saharan Africa through its sub-regional organizations (SROs) and the national agricultural research systems (NARS).

SABIMA builds stewardship capacity that will be valuable if and when countries decide to admit biotech products for commercial use. A special feature of the project is its emphasis on the creation of awareness for issues of stewardship in biotechnology and the provision of training to scientists, policymakers and farmers in stewardship and its application to the development of improved crops. The training in biotechnology stewardship is unique in Africa.

The six SABIMA countries are Burkina Faso, Ghana, Kenya, Malawi, Nigeria and Uganda. The project, which started in 2009, ends in 2011. The project countries in their various reports to FARA and the SFSA have recounted success stories on the application of the stewardship principles in their research and technology transfer activities. These have ensured quality product development and the general responsible management of biotechnology. FARA and SFSA feel that these experiences in stewardship should be documented and shared with the rest of the world.

We have therefore encouraged the staging of the *First Pan-African Conference on Stewardship of Agricultural Biotechnology* in Accra, Ghana, from 28 to 30 November 2011. It provides an opportunity for the project countries to showcase their experiences through the presentation of Case Studies and to learn further from the experience of private sector agencies with longer-term experience in applying the stewardship principles to product development and marketing.

We hope that these Case Study Reports will be useful to all the countries of Africa examining the crucial topic of stewardship in agricultural biotechnology and its potential use by the continent's farmers.



Prof Monty Jones
Executive Director
Forum for Agricultural
Research in Africa



Dr Marco Ferroni
Executive Director
Syngenta Foundation for
Sustainable Agriculture

Case Study Process

The idea of using case studies came at the end-of-year review meeting for SABIMA in 2010, as a way to share stewardship experiences. The stewardship leaders had applied stewardship principles in their biotechnology laboratories and trained coworkers and scientists, and were enthusiastic to share learnings and lessons to an ever-increasing audience throughout Africa and the world. The case studies provide a platform for stewardship leaders in Burkina Faso, Ghana, Kenya, Malawi, Nigeria and Uganda to share how they succeeded in implementing and integrating stewardship practices and principles into their work on research, development, and commercialization of biotech crops. In these 12 case studies, the stewardship leaders share first-hand accounts of the challenges they faced and the solutions they found. They tell how stewardship helped their labs run more efficiently, ensured product integrity and improved regulatory compliance.

At the review meeting, stewardship leaders discussed specific activities and points of learning where they had made interventions and changed their working practices as a result of the SABIMA programme. These have been developed into case studies. To identify a case study-worthy idea, scientists thought of a 'trigger' event, something that happened, causing problems or challenges for their lab or programme. These ranged from false negative PCRs for inserted transgenes to improving best practices for international transportation. Some case studies involved the application of stewardship principles to non-GM crops.

The case studies also enabled the scientists to develop skills on sharing experiences and effective written communication. The cases were written in an interview-based style with stewardship leaders

providing their opinions and experiences; a style different to writing most scientific papers or project reports. The goal is to spread individuals' own examples of incorporating stewardship into their biotechnology work – from the lab, greenhouse, field, and commercialization to product discontinuation. African scientists can now learn from each other on stewardship. Ideally, colleagues and other scientists will recognize situations they have also encountered, and can capitalize on the stewardship solutions suggested in the cases. In most cases, a step-by-step approach is illustrated, so scientists can immediately tailor and implement the best practices in their programs.

Case study writing process:

1. *Self-reflection*—Each scientist reflected on recent challenges in their program, especially those overcome through implementing stewardship.
2. *Trigger event*—They brainstormed a 'trigger' and surrounding situations with the editor, and discussed the compelling points, challenges encountered, impact on the larger project, and key lessons. The goal was to identify a case focus that would yield clear learnings and be applicable to a wider audience.
3. *Process*—With points from the brainstorming session in mind, the scientist started writing using guiding questions created by the editor. Questions covered the actions taken, trigger event, stewardship lessons, impact of SABIMA training, key challenges, communication strategies, and take-away lessons.
4. *Editor review*—The editor reviewed the author's responses, formulating follow up questions to help the author fill in gaps or illustrate important learning points in more depth.
5. *Follow up Interview*—The editor then conducted an interview where the author verbally responded to the follow up questions. The responses were typed by the editor verbatim, allowing the author to explain ideas freely and for the author's voice to clearly come through in the text. The editor then asked additional probing questions to address underlying points and cover lessons in more depth.
6. *Final Editing*—To continue the learning process, the draft was reviewed and edits suggested for incorporation by Syngenta Foundation for Sustainable Agriculture (SFSA), Forum for Agricultural Research in Africa (FARA) and the SABIMA consultant trainer.
7. *Approval*—The final version was reviewed and approved for publication by the author's research institution.

Case Studies: Uganda

Incorporating Stewardship Practices into the Development of Genetically Modified Banana

Stewardship leader:

Dr Andrew Kiggundu

Location:

National Agricultural Research Laboratories
(NARL) – Kawanda, Uganda



In Uganda, the cooking banana is referred to as “matooke,” and is synonymous with “food” in a large part of the country. As the leading starchy staple, Uganda currently produces 11.1 million tonnes on 1.8 million hectares (FAO 2009), with per capita consumption being the highest in the world. Banana is increasingly grown as a cash crop, spreading to non-traditional banana growing regions due to its food security importance. While a range of cultivars are found in Uganda, over 85% of banana is of the East African Highland Bananas (EAHB) group of cooking bananas. However, production stability and yields have declined in the last decade, reducing plantation life from 50 years to 3-5 years, and yields from 20 to 6 tonnes per hectare (Gold *et al.* 1999). This decline has been attributed to diseases (most critical), nematode and insect pests, poor soil fertility, and other socio-economic factors.





Bananas in Kampala, Uganda. As the staple food, banana is sold in nearly every market throughout the country.

New, disease-resistant banana varieties are considered a highly sustainable and cost-effective approach to managing diseases, especially for subsistence farmers with low capital input. Work with hybrids has had limited success, especially since the progeny lack the preferred taste and cooking quality. Conventional breeding for various disease resistances has also been largely unsuccessful, with germplasm lacking the necessary resistance genes. While there is strong demand for varieties with pest and disease resistance, they must combine resistance traits with locally acceptable post-harvest characteristics. Genetic engineering (GM)

offers the possibility of introducing such traits into acceptable cultivars, without altering preferences.

To explore GM and other complementary options, a project was established focusing on improving EAHB varieties through enhancing their ability to resist fungal pathogens, nematodes, and weevil pests, whilst maintaining their desirable post-harvest/culinary properties. The Government of Uganda, Rockefeller Foundation, USAID and the Bill & Melinda Gates Foundation are financially supporting the National Agricultural Research Organization's (NARO) National Banana Research Programme's Biotechnology projects. Research partners are Bioversity International, Makerere University, Catholic University of Leuven, University of Pretoria, Leeds University, the Centre de Coopération Internationale en Recherche Agronomique pour le Développement (CIRAD), and the International Institute for Tropical Agriculture (IITA) to conduct the research. Over the last five years NARO's banana team has developed a standard process for development of GM bananas involving various stages from banana somatic embryo culture formation, transformation through to field evaluation in confined field trials (CFT) (Figure 1).

A NARO scientist undertaking a banana transformation experiment



The initial research effort was to transform the local bananas that had never been transformed before. Several protocols to transform international banana cultivars existed, but these did not work for local cultivars, foremost being EAHB. Scientists at NARO's Banana Research Programme started from scratch to first develop a regeneration system based on somatic embryogenesis from immature male flower primordial tissues. The successful protocol was continuously improved upon through experiments on the production of somatic embryogenic

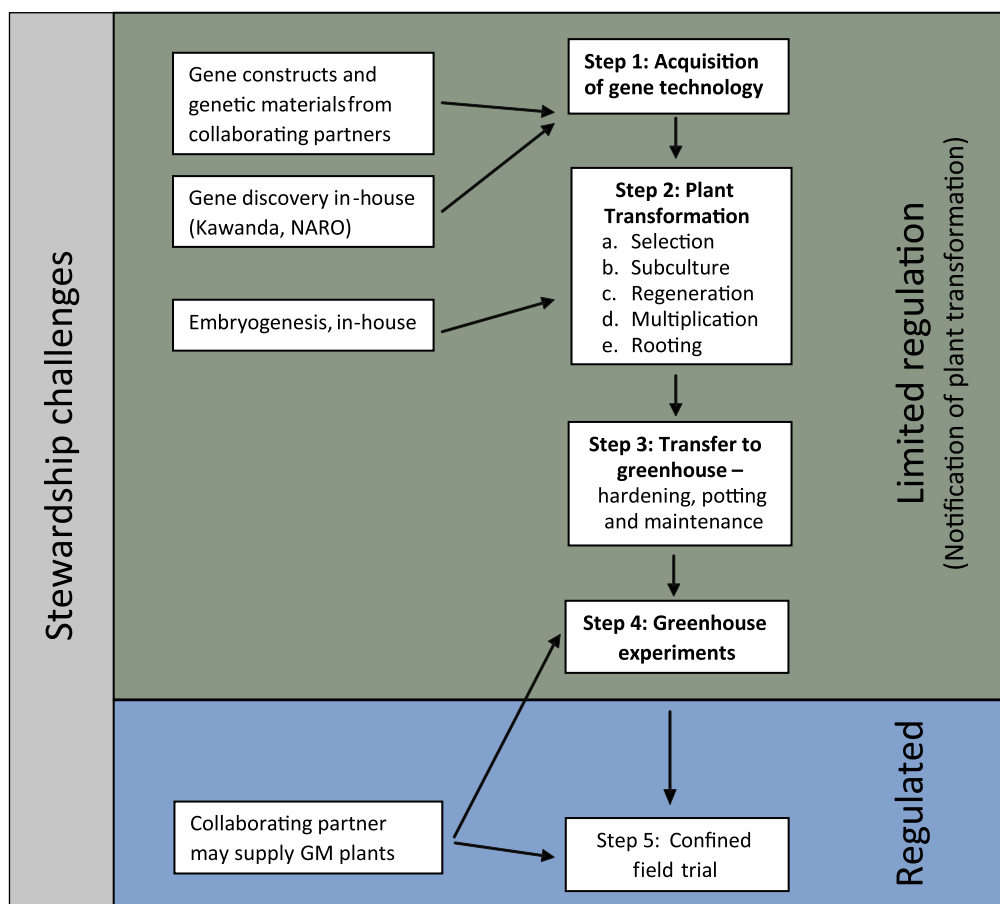


Figure 1. Stages of banana GMO development and stewardship challenges

cell cultures, regeneration and transformation efficiency. Research continues on transforming more preferred and highly commercial banana cultivars. Many of the protocols were just written in laboratory notebooks as different scientists and project teams had slightly different preferences for the steps, while new methods had to be incorporated from time to time.

During the SABIMA project, the research team realized that it was important to standardize the transformation protocols with the development of standard operating procedures (SOPs). With the guidance of the Banana Programme team leader, Dr Wilberforce Tushemereirwe, teams drafted SOPs for the transformation, greenhouse handling and testing and field trials. The team working on the banana transformation SOP was led by Dr Geoffrey Arinaitwe, a participant in the SABIMA stewardship training modules I to III. The drafts were later reviewed in a SOP development meeting in which CCPs were identified and measures developed to address those CCPs in the transformation SOP (Table 1) and improvements incorporated. To show that the process is continuous, we recently added a new PCR check for cultivar of the embryogenic cell lines before transformation.

Table 1. Critical control points in GM banana development

Development Step	Critical Control Points	Regulatory Compliance or Stewardship
Step 1: Acquisition of Gene Technology	Obtain all necessary documentations with gene acquisition from partners including: 1. Vector maps 2. Names/function of genetic elements 3. Primer sequences 4. Full sequence of gene	Stewardship
	Verification of genetic material via: 1. Restriction analysis 2. PCR with specific primers 3. Sequencing vector inserts	Stewardship
Step 2: Plant Transformation	Obtain banana embryogenic cell cultures with relevant information 1. Cultivar 2. Cell line number 3. Age of cell line 4. Date of last subculture	Stewardship
	Verification of cultivar of cells obtained 1. PCR with genome specific primers 2. Cell culture appearance	Stewardship
	<ul style="list-style-type: none"> • Completion of transformation form • Derivation of code • Unique labelling – use computer generated labels • Transformation with gene of interest and <i>gus</i> gene control • Separation of different experiments in space or time during subcultures 	Stewardship
Step 3: Transfer to Greenhouse	<ul style="list-style-type: none"> • Completion of greenhouse form • Unique labelling • Water proof labels on both pots and plants • General plants maintenance • Records of plant death 	Stewardship
	Confirmation of transgenic plants by PCR 1. Use of gene specific primers 2. Use combined gene and promoter primers 3. Use of actin primers 4. Use of agrobacterium primers 5. PCR plants at 2 months old	Stewardship

Development Step	Critical Control Points	Regulatory Compliance or Stewardship
Step 4: Greenhouse Experiments	<ul style="list-style-type: none"> • Ensure organisms being tested are virulent • Ensure additional staff are trained • Labelling • Data collection • Inoculation of plants • Sanitation of working areas • Containment • Managing waste materials 	Stewardship
Steps 5: Confined Field Trials (CFT)	<ul style="list-style-type: none"> • Make sure application materials required by regulation are complete • Include agreements with partners • Details of genetic elements and reference publications 	Stewardship and Regulatory
	<ul style="list-style-type: none"> • Ensure all confinement provisions are met in the application and adhered to during the whole trial process 	Stewardship and Regulatory
	<ul style="list-style-type: none"> • Ensure adequate capacity is provided for the data handling, management analysis and reporting 	Stewardship

1. Gene technology acquisition

Genes are generally obtained two ways. Most commonly, the program acquires genes from international partners with whom NARO has established research and/or material transfer agreements. Usually the genes are in-plant transformation vectors with the appropriate promoter and subject to international containment regulations as provided in the Cartagena Biosafety Protocol.

The second type of gene acquisition is in-house gene discovery and cloning. This mainly takes place with graduate student projects where homologue genes from other species are isolated and characterised *in-silico*, and then used in transformation in order to over-express them for evaluation. In such instances NARO staff have successfully acquired, cloned and registered the genes with National Center for Biotechnology Information (NCBI).

This part of the process because it is laboratory research and fully contained it is not regulated in same way as confined field trials. The guidelines only require a notification to the National Biosafety Committee (NBC) through the Institutional Biosafety Committee (IBC) when genes have been acquired and are ready for plant transformation.

Challenges for stewardship:

1. Confirmation of vectors received from collaborators has always been done, but only at the level of restriction analysis. Restriction analysis only gives expected fragment size but not the expected gene sequence.

2. Insufficient gene technology information/documentation from partners. In some instances the partner may ship genes in vectors soon after they have completed constructing the vector and are still making the final documentation. There are delays in getting correct restriction maps, vector maps, and sequence information especially of primers needed.
3. Agreements need to be well thought out and understood by both partners. If the research agreement (usually a general project grant agreement) does not specify conditions for material exchange, another materials transfer agreement needs to be signed by partners. In the past, NARO lawyers, African Agriculture Technology Foundation (AATF), and Uganda National Council for Science and Technology (UNCST) have assisted with such documents.
4. Graduate students working in gene discovery require monitoring and new gene sequences/vector construction must be confirmed.

2. Plant transformation, selection and regeneration

For banana transformation, the starter materials of choice are embryogenic cell suspension cultures. These cells are individual embryos that when transformed will generate back into normal plants. This stage starts by preparation of the vector into an appropriate agrobacterium strain and growing it to required levels. Once those are ready, cells are acquired from the cell development team and several transformation experiments are performed by co-cultivation of banana cells with agrobacterium, through washing and then recovery on regeneration medium containing the selection marker, kanamycin. A control experiment with *gus* gene containing vector is done to confirm that transformation was successful through performing transient assay after cell recovery.

The regeneration stage is long, typically 9 months, in which sub cultures are done every 2 months onto fresh media to remove contaminations. As kanamycin kills non-transgenic cells, transgenic ones gradually develop into callus structures referred to as clones. These are picked and transferred individually onto regeneration media so they can develop shoots. Once the shoots fully form into plantlets, these are cut back and cultured on proliferation media to generate copies of the same line as required for downstream experiments. Once the required

Left: Transformed cells in advanced stages of kanamycin-mediated selection

Right: Transformed plantlets growing in nutrient-rich medium



number is reached, they are then transferred to rooting media and then to weaning chambers in the greenhouse.

Molecular analysis with PCR to confirm transgenic plants can be done here with appropriate agro-bacterium controls to avoid false positives due to residual agrobacterium.

Challenges for stewardship:

1. Labelling is critical at all stages. From the tubes with the agro-bacterium, and flasks of embryogenic cell cultures. Any misidentification can lead to mixing and eventual non-accuracy in the products developed.
2. When working with several cultivars, careful separation of the different cultivars is important, either through work schedules (time separation) or use of colour codes and cultivar/gene/project specific containers.
3. Positive control with *gus* gene at transformation allows one to confirm transformation and that the cell line used was viable.
4. Development of a molecular PCR test for transgenic plants, including a housekeeping gene control such as actin to troubleshoot PCR problems.
5. Molecular PCR analyses when potted plants are at least 2cm tall. By this time, agrobacterium has been completely removed and will not give a false positive
6. Number of subcultures during the multiplication stage should be kept to a minimum as increased subculture numbers leads to increased somaclonal variants and off-type plants.

3. Greenhouse hardening and maintenance

On completion of transformation, selection, and multiplication, plants are rooted *in-vitro*. After roots are fully formed, they are transferred to the greenhouse for hardening. The greenhouse is a Biosafety level-II certified by Uganda's National Biosafety Committee (NBC). The plants are transferred to small cups and into a high-humidity chamber for hardening. It takes about 3 weeks before they are then transferred to bigger pots with a soil mixture. Records are kept of plants that die and after 2 months PCR is done to confirm transgenic plants.

Challenges for stewardship

1. Several plants may die during the hardening stage. Care should therefore be taken when handling the tender plants during transfer.

Transgenic banana plants hardening in the greenhouse



2. The humid chambers are very wet and labels can easily be lost. There is need to take care that labels are waterproof, and that pots are properly labelled. Also different size chambers allow the separation of different groups of plants to avoid inadvertent mixing.
3. Once plants have been transferred to bigger pots double labelling is used - both on the plant and pots.

4. Greenhouse/screenhouse experimentation

Greenhouse and screenhouse experimentation tends to be highly specific depending on the project. Past experiments to test transgenic plants for bacterial wilt and nematode resistance have been performed on a large number of plants.

Challenges for stewardship

Scientists need to ensure that they have adequate inoculum of the pathogen or pest they intend to evaluate. Some laboratory-grown strains tend to lose virulence and using them to select plants to advance may not lead to the desired effect. Using adequate controls can solve this problem. However, there needs to be a large number of replicates which may not be readily available in banana.

Labour requirements are high at this stage. Banana plants need to be potted, tested, and arranged properly to avoid data mix-ups.

5. Confined field trial evaluation

This step of the development process is highly regulated in Uganda through the National Biosafety Committee (NBC) of the Uganda National Council for Science and Technology (UNCST). Comprehensive SOPs have been developed and published for CFTs. The applying Ugandan institution, with a fully formed Institutional Biosafety Committee (IBC), must submit a rigorous application explaining all details of the proposed CFT and crop.

*Left: Banana team scientists plant a confined field trial at the National Agricultural Research Laboratories, Kawanda.
Right: The growing GM banana CFT.*



Challenges for stewardship

1. To be good stewards of the technology, scientists must be highly responsive to biosafety and regulation. The list of regulatory requirements can be long and can only be achieved through good teamwork and training all the staff that will work with the trial, including non-scientific staff such as security guards.
2. Compliance can be challenging when several overlapping activities are specified. For example, there is no need to combine isolation distance with flower removal for biological containment; the project would be unnecessarily strained.
3. Reporting incidents properly is critical to stewardship and official guidelines tend not to be perfectly clear regarding what constitutes an incident. Many occurrences that researchers see as common, such as hail storms or unusual plant phenotypes, constitute incidences that need to be reported.

Conclusions

The SABIMA project was an eye opener for Dr Kiggundu's group in terms of streamlining the development of transgenic banana, harmonising best standards, and reinforcing good practices to ensure product integrity and full regulatory compliance. 'We were able to pull together the different transformation protocols into one best practice protocol, and create SOPs with a unified recording system based on easy to understand codes. By identifying the different critical control points, new procedures were integrated into the standard operating procedures. We have managed to avoid many issues of mixing that had affected our projects in the past,' explains Dr Kiggundu.

Lessons

- Outline the development process before writing a SOP and trying it out to make sure it is successful.
- Once a system is clear and working, look for what can go wrong at each step (critical point) and then develop procedures to avoid or minimize the potential issues.
- Training is critical for a program to run effectively. All staff should be trained in stewardship principles and methodology including, safety, quality and sustainability, product integrity, containment and confinement, and regulatory compliance.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Andrew Kiggundu** at akiggundu@kari.go.ug.*

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Ensuring product integrity in transformed bananas through molecular verification

Stewardship leader:

Ms Sarah Nanyiti

Location:

National Agricultural Research Laboratories
(NARL) – Kawanda, Uganda



Bananas are the main staple food for Ugandans and are grown all over the country on 1.8 million hectares, equivalent to 38% of Uganda's arable land (Tushemereirwe *et al.* 1999). About 65% of Ugandans eat some form of banana daily, with consumption in rural areas much higher than in towns (Uganda Bureau of Statistics 2010). However, banana does not provide the minimum daily requirements for iron and vitamin A, with one banana providing only 1.4% of the minimum requirement of iron and 6.8% that of vitamin A for pregnant women (USDA Nutrient Database 2011). These micronutrient deficiencies result in clinically malnourished children in Uganda and throughout the developing world.

Uganda's banana biofortification projects aims to substantially increase the levels of bioavailable iron and provitamin A to improve food security. The project is a collaboration between the National Agricultural Research Organisation, Uganda (NARO) and Queensland University of Technology, Australia (QUT). Researchers insert genes that increase beta-carotene (precursor to vitamin A) and iron into banana embryonic cell suspensions using *Agrobacterium*-mediated transformation.

Agarose gel electrophoresis – the upper lane shows a gene-specific PCR. Plants with bands are positive for take-up of the transgene required for successful genetic modification. The lower lane is agrobacterium check. The plants tested were negative – they did not contain the inserted gene.



Product integrity is very important. This means ensuring plants contain exactly the genes and expression levels intended. The transgenic banana plants are checked for the presence of the intended genes using molecular verification with PCR and primers specific to the genes of interest. There are sets of primers for each of the transgenes used. PCR is done at every stage: plantlet regeneration in tissue culture, hardening in the greenhouse/glasshouse, and prior to planting in the CFT. In the CFT, researchers study agronomic characteristics and select the best lines for further product development.

It is imperative that only positive transgenic lines are used in the CFT. As Nanyiti explains, 'It would be a serious setback to take a plant through all the stages – transformation, greenhouse, CFT – only to find that the line does not contain the genes of interest. We are concerned about delays in the science programme and wasting research resources, but also about the good reputation of the scientific work conducted at NARO. Maintaining the confidence of governmental regulators, our research collaborators and funding donors is vital.' In their CCP analysis, the NARL team identified verification of the presence of the transgene as a CCP for product integrity and developed an SOP for the PCR screening process. All staff conducting molecular verification now follow this SOP.

'The motivating event for developing the SOP was the observation that the majority of PCR verifications were coming up negative, seemingly indicating that the first inserted gene had not been integrated in the plants,' says Nanyiti. Knowing the gene should be present, the team looked through the literature and thoroughly examined the PCR process and its many influencing factors. The researchers changed primers and reaction temperatures, but none generated the expected positive readings.

'PCR is a highly sensitive reaction, with many factors able to prevent it from running successfully,' Nanyiti explains. 'The reaction uses an enzyme called Taq, which can be easily blocked by the many inhibitors present with the DNA in solution from the DNA extraction process.' To reduce the inhibitor concentration, the DNA solution can be diluted, but only to a level at which the PCR can still multiply enough fragments to show clearly on a gel. Once the NARL team diluted the DNA appropriately, the PCR results came up positive (70% of samples tested positive) for each of the inserted transgenes tested. Hence careful monitoring of DNA/inhibitor concentrations is now considered a CCP.

Another key factor that can affect product integrity is labelling. Whenever staff suspect there could be a labelling problem in the greenhouse or CFT, all the plants are resampled and molecular verification is performed. 'For example,' says Nanyiti, 'if staff suspect a mix-up between plants transformed with genes for increased iron content and provitamin A plants, we sample each plant and test it with both the primers targeting iron content genes and provitamin A genes. This way we can tell which gene we have inserted and guard against late-stage errors.'



Carefully labelled banana tissue culture plantlets in a growth chamber.



Banana plants hardening in the Kawanda greenhouse before transfer into the confined field trial.

Challenges

To maintain the highest research standards and ensure that product integrity is maintained throughout the research programme, all staff need training in stewardship principles. Fortunately, the principal investigator of the biofortified banana project at Kawanda raised the need for this training early. Nanyiti emphasises that ‘All staff involved in development of transgenic lines need to know how their actions can work for or against the integrity of the product developed. When everyone in the team of scientists and technicians understands how everything they do affects the whole project, they are supportive of this new systematic approach. Creating change to established ways of working is never easy but after training and awareness about the compelling reasons for good stewardship there is now no resistance to the verification steps in the new SOP.’

Stewardship

‘SABIMA training sensitised scientists involved with biofortified bananas to the key stewardship principles along the chain of product development,’ Nanyiti reports. The concept of product integrity was particularly valuable. As a result of the training, molecular verification is now done at each critical stage of the programme:

1. When new DNA constructs and research samples arrive, staff test to ensure these contain the correct genes

2. After initial transformation, when the embryonic cells develop into plantlets in the growth chambers
3. When the plants are transferred from the tissue culture lab to the greenhouse
4. In the field, at the CFT

To spread the practice of molecular characterisation verification, NARL shared this new approach of CCP analysis and use of new SOPs with other scientists at Kawanda and its sister institute, the National Crops Resource Research Institute (NaCRRI). NACCRI scientists have visited NARL and shared ideas during bench trainings on SOPs and CCPs in PCR analyses.

Lessons

- Verifying plant material for the presence of transgenes throughout the whole plant research and development programme is an important stewardship practice and critical to product integrity.
- It is not just a matter of looking at a problem in isolation and choosing a solution, but adopting a thorough investigative approach using CCP methodology. This requires a thorough knowledge and understanding about the processes involved. Also detailed scientific skills are needed for methods such as PCR, to be able to identify technical problems and find practical and cost-effective solutions.
- ‘Excellent product stewardship and good scientific method are inter-linked and complement each other,’ highlights Nanyiti. ‘Combining best practices and thinking from both approaches will bring quality results, scientific progress and regulatory compliance. All are needed to maintain and build confidence in the science programmes, gain trust of our stakeholders, research partners and governmental officials and secure funding for delivery of our critical mission – developing bananas with improved levels of micronutrients to reduce malnourishment in Uganda.

*For more information on the experiences and stewardship principles covered in this case, please contact **Ms Sarah Nanyiti** at wassanyis@yahoo.com.*

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Case Studies: Ghana

No Need to Panic When Office Data Vanish: Format for Backing Up Information

Stewardship leader:

Dr Marian D Quain

Location:

Council for Scientific and Industrial Research (CSIR),
Crops Research Institute (CRI) – Kumasi, Ghana



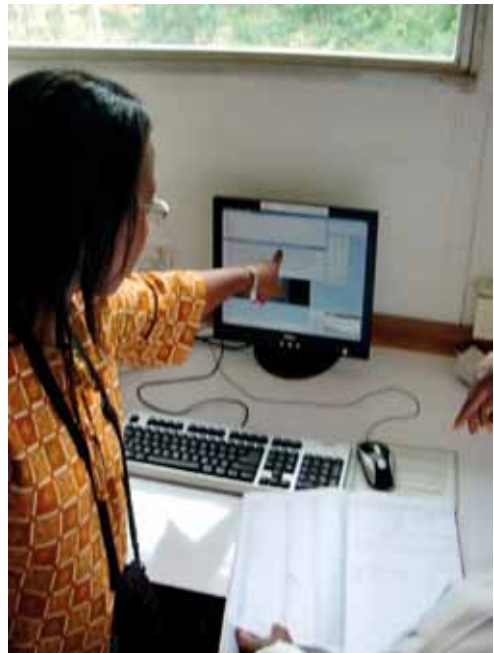
At Ghana's Crops Research Institute, laboratory computers store data from current experiments, while the office computers hold reports and all experimental analysis for the past 5 years, along with the licensed software to assess the data. In the past, weaknesses in the internet firewalls have caused computers to crash, with subsequent data loss. In 2010, technical personnel reformatted Dr Marian

Quain's computer in an attempt to fix a booting error, deleting all files and software, and she was left unable to retrieve any data.

Software costing over USD 250 that could only be installed once was lost, forcing Dr Quain to find funds to obtain new software for analysing her data. Since it is not possible to secure such software online when operating from Ghana, it took additional time, effort and funds to do so. Quarter and annual reports on project activities and proposals were all lost to this incident. Publications that were almost complete had to be restarted and parts of the experiments that run

over six months had to be repeated. Some of the lost reports were being used to develop articles for publication so the writing had to be done again and raw data had to be re-analysed for publication. Before, when writing a report on project activities, it was just a matter of developing on the previous report. This was no longer possible and more time had to be spent.

‘It was clear we needed a standard operating procedure (SOP) for a range of problems staff can face when dealing with computer incidents,’ Dr Quain commented. One critical control point (CCP) identified was when a computer does not boot correctly. When something is labelled a CCP, now staff and scientists take it more seriously. This was not the case previously with the booting error. With widespread computer literacy and familiarity, staff can often assume they know all, but Dr Quain stresses with the CCP it is vital the computer experts in the department or software suppliers are called to assist in solving the problems.



Dr Quain instructing a laboratory technician on computer protocol.

Dr Quain created the SOP together with the unit’s chief technician, the person whom the changes would most directly affect. The ‘Using Computer in Office’ SOP (Appendix A) covers a range of topics. These include regulating access to Dr Quain’s computer and office, leaving them open to scientists, but with other lab staff needing to request permission. Employees using a USB drive must now sign in, so that if a problem does occur, it is easy to track who was responsible.

It is also important to back information up properly. ‘Fortunately, I additionally had most data on a communal external hard drive,’ Dr Quain notes, ‘but it took hours to find because we didn’t have any data labelling guidelines at that stage.’ The SOP addressed this point, and now computers are backed up weekly with all documents in named folders indicating the computer, project and date of the backup, for easier retrieval and tracking.

As a result of the SOP there have not been any further incidents resulting in loss of data. Staff now also spend less time looking for data. ‘The computers still freeze occasionally,’ Dr Quain explains, ‘but since all the staff now know what to do, there have not been any problems.’

Stewardship

Management systems, such as those required by stewardship, rely on high quality and accessible documentation. This can be on paper and/or held as electronic copies as part of an

information management system (e.g. database). Managers need to put security systems in place to prevent data loss through technical failure, human error or malicious intent.

Furthermore Dr Quain, a SABIMA certified Biotechnology Stewardship Trainer, believes that ‘one critical aspect of stewardship is documenting actions taken when an incident occurs. It is very important to identify responses and improve ways of working, in order to avoid the problem in future. Creating best practice SOPs and communicating them to staff are essential steps in building a more productive work environment and becoming proper stewards of the technology employed.’ How thoroughly staff follow SOPs is monitored routinely at laboratory meetings. As experiments are carried out, if there is an existing SOP, staff are reminded to follow it, and if there is not, they are encouraged to develop an SOP for the activities.

Implementing stewardship principles, SOPs and CCPs from the SABIMA training have had a tangible impact on many facets of Dr Quain’s lab and research programmes. Regarding team and department decision making, members now realize that in case of an incident, there is documented information that can guide them on how to deal with it. There is a chain of communication and documentation of incidents to ensure that they are properly resolved. Safer conduct inspired by stewardship processes ensures that funds are not spent on managing

situations that could have been avoided and that product integrity is ensured so experiments do not need to be repeated to generate the needed result. Stewardship has also helped enhance donor confidence and support. Since the implementation of higher quality of reporting and research results, the donors are confident the funds are being managed well and have therefore promised to renew funding of projects.

Research Staff Reaction: David Appiah-Kubi

‘The SOP serves as a daily reminder of how to do routine work in the lab. It is especially helpful after long absences from certain duties. It also serves as a guide for new trainees in the lab. Writing an SOP has brought to mind the need to document every activity in the lab. Doing so has improved the general lab work ethic and procedures.’

Communication

‘It was important to communicate the SOP, and subsequent changes, to the research assistants and technicians who would be most affected,’ Dr Quain emphasizes. ‘Some of the research assistants were involved in the development of the SOP and therefore had a hands-on understanding of it, but other staff had been less involved.’ The SOP and changes were announced at the weekly staff meeting, posted by the office computers, and hard copies given to all relevant staff.

Through the steps taken to create the SOP, ‘lab staff also noticed other areas of data management and documentation that needed improvement,’ adds Dr Quain. Since documentation was identified as an issue, all records are now kept in triplicate. For example, when tissue culture material is received, a lab technician documents its status in a lab notebook and then writes a report for the researcher, who shares it with the project coordinator. By having triplicate copies, if one is lost, staff can always locate another copy. Dr Quain explains that ‘the lab has changed its whole way of thinking on protecting information. Since we took up developing

SOPs and identifying CCPs, staff have taken data documentation seriously. They now believe that anyone could check on the data at any time. The mentality is also that collaborators can call on us at any time to produce reports and data must be easily accessible by program leader and all stakeholders.'

Lessons

- 'Effective communication and involvement of key personnel determine if a group really uses an SOP,' says Dr Quain. She carefully shared the SOP and 'lessons learned' with the Institute's technical unit, the people responsible for computer maintenance, repairs and internet connectivity. As a result, they supported adoption of the SOP throughout the institute. When scientists consult the unit about computer malfunction, part of the follow-up action is to share the SOP and help with implementation.
- Data is meant to be shared and it needs to be managed properly and stored in an easily traceable manner. It needs to be backed up and emailed to the programme leader, that way the information can be easily obtained online anywhere in the world. Software should be purchased to serve more than one computer.

Appendix A:

Council for Scientific and Industrial Research-Crops Research Institute Standard Operating Procedures

Section: 4	Document: 03	Version: v.01	Draft: 01
Title: Standard Operating Procedures for USING COMPUTER IN OFFICE			
Author	Name: PRISCILLA A. BOATENG Date: 17/05/2010	Signature:	
Approval	Name: MARIAN D. QUAIN Date: 21/05/2010	Signature:	
Approval	Name: Date: 21/05/2010	Signature:	
Issue Date: 21/05/2010		Effective Date: 21/05/2010	

Crop Research Institute

STANDARD OPERATING PROCEDURES

Introduction: Computers in the office of the Research Scientists, are for record keeping and any other official work. This guidelines seeks to make sure the computers are put to the proposed use, data stored properly and documentations are easily accessible.

Objective: Offer guideline for the use of computers in our offices.

Scope: This guideline applies to all staff in the Biotechnology laboratory and students who come to the lab to work.

Terms/Definitions:

Responsibilities and procedures:

1. The computers in the office have a password and users should contact researchers using the computers to login.
2. Computers in the office can be used by others only when researchers working in the office have been informed.
3. Computers are strictly for official work only and downloading of music and movies is forbidden.
 - a. As such music and movies should also not be uploaded onto the computers
4. When saving documents on the computer, create a folder for each month and within that folder, create another folder for each project before saving the documents.
5. Backing-up of documentation on the external hard-drive should be done weekly, ensure you back-up into the correct computer folder on the external hard drive.
6. Contact computer unit for any problems associated with the computers.
7. Drives used on the computer should always be scanned.
8. Preferably, to send information from one computer to the other, use the internet or the pendrive that is formatted.
9. Always check the status of antivirus and update when necessary. Contact suppliers (Dealers on 0246555444/0243462193) when necessary.

International movement of in vitro plants

Stewardship leader:

Dr Marian D Quain

Location:

Council for Scientific and Industrial Research (CSIR),
Crops Research Institute (CRI) – Kumasi, Ghana



CRI and a Latin American research institute have a partnership to investigate field performance in Ghana of drought-tolerant cassava (*Manihot esculanta* crantz) varieties selected through breeding activities. Cassava alone accounts for 34% of food crop consumption per annum (MOFA 2003). It is also a regular source of income for most rural dwellers, contributing 22% to the agricultural gross domestic product. Cassava is the most important vegetatively propagated food crop and the second most important food staple in terms of calories per capita in Africa (Nweke *et al.* 2002). Ghana is the third largest African producer of cassava with over 10 million tonnes annually (FAO 2009) with production covering more Ghanaian land area than any other crop.



The research collaboration involved moving fragile living tissue-culture plantlets between Latin America and Ghana, with communication around shipments proving critical. In 2008, an unexpected incident occurred that had a major negative impact on progress in the programme. Cassava plantlets with well-developed shoot and roots in baby food jars with nutrient medium were sent from collaborators to CRI for sub-culturing, hardening and field establishment.

Unfortunately, there was miscommunication concerning the shipment details and on arrival at the Accra airport the shipment was held in customs for phytosanitary inspection. For approximately three weeks, the plantlets sat in a cardboard shipping box with no light and above optimal temperatures. By the time the plantlets reached the Kumasi laboratory 270 kilometres north of Accra, all of them were dead. No materials could be established in the

Tissue culture plantlets, recently received from partners in Latin America.



Box 1: SOPs developed

1. *General use of the biotechnology laboratory*
2. *Standardisation of laboratory equipment*
3. *Using the pH metre*
4. *Distillation point*
5. *Sampling procedure for DNA extraction on station*
6. *Sampling procedure for DNA extraction off station*
7. *Labelling DNA extracts*
8. *Preparing DNA for export*
9. *Receiving tissue culture materials*
10. *Initiating cultures*
11. *Sub-culturing*
12. *Acclimatising cultures in screenhouse or greenhouse*
13. *Preparing stock solutions*
14. *Using autoclave*
15. *Using the laminar flow hood*
16. *Using the fume hood*
17. *Cleaning glassware*
18. *Handling contaminated cultures*
19. *Disposal of laboratory waste*
20. *Agarose gel preparation*
21. *Gel electrophoresis*
22. *Using the gel capture for analysis*
23. *Polyacrylamide gel preparation*

screenhouse and the project had no data to show for an entire year, a costly setback.

A similar experience occurred with DNA samples, which had been packaged in 200µl PCR tubes on ice packs, were held in customs and eventually sent to a partner in India 12 months later. It was clear from these two episodes that a new communication plan was needed for transportation of perishable samples. Dr Quain turned to the stewardship principles and practices she learned during the SABIMA stewardship training and started identifying CCPs for plant shipment. Rapid and thorough changes were implemented, now SOP ensures that samples are stable while in transit and have clear handling instructions. All documentation about the materials transported, together with the tracking numbers, are emailed to the partner beforehand. Boxes are labelled that contents are temperature-sensitive and should be kept at 4°C for DNA and 25°C for live plants both within customs and during delivery. Since most ports of entry in Ghana cannot accommodate the 4°C requirement, customs officials are sensitised on the need to quickly process them.

Formalising stewardship practices on safe management during shipping are just one example of how Dr Quain's lab has embraced stewardship. When she engaged her staff

in developing shipping CCPs and SOPs, they started generating SOPs themselves for all their other research activities. By March 2011, Dr Quain's staff had generated 23 SOPs (Box 1).

All staff members insist on having copies of all the SOPs for reference. Soft copies enable them to improve the thoroughness of their work and continue to make improvements to their CCPs and protocols. This 'grassroots' ownership on the part of the laboratory scientists and technicians is key for stewardship principles becoming imbedded in the everyday working environment. The entire laboratory has a new mentality and approach to scientific safe practices. Staff members turn each new problem into a trigger event for application of the CCP identification approach to identify the cause and then to address and mitigate the risk.

Stewardship

Dr Quain explains: 'The SABIMA training made me aware of what I can do when incidents occur and the need for an effective communication plan. I realised through the training that I cannot assume that everybody knows what to do, hence the need for SOPs on all research activities.'

Staff reactions on developing SOPs:

SOPs allow for efficient and effective operations with predictable and replicable results. This enables new colleagues in the lab to easily practice the same procedure, perfected over the years.

- **Linda Abrokwah**, molecular biologist

SOPs provide a systematic way of working, avoiding errors while obtaining quality assurance and controlled results.

- **Charles Afriyie-Debrah**, biosafety officer

CCPs and SOPs help to prevent infections and mislabelling in cultures, producing clean and healthy planting materials, and by following instructions on using lab equipment, it is easier to follow safety measures to ensure biosafety in the laboratory.

- **Monica Ode Adu-Gyamfi**, tissue culture technician

Challenges

To ensure that quality SOPs were developed, and that all staff thoroughly understood the stewardship principles, Dr Quain reviewed all the CCPs and SOPs and gave critical feedback. She pointed out ways they could fine-tune their documents. 'While identifying CCPs were not a problem,' she said, 'indicating the processes, critical limits, and measures to resolve issues, proved more difficult.' Dr Quain coached her staff on how to think through these challenges, and then develop sets of responses to potential issues.



Clearly labelled package for shipment.

Transporting international samples provides a good example. When shipments reach the international port in Ghana, money is needed to pay custom fees and handling charges so the samples can be picked up. 'At CRI, the administrative and accounting process takes about seven days, far too long for fragile materials waiting in customs,' explains Dr Quain. By involving staff in the administration and accounts departments and developing good communication with them, funds are processed more quickly for this time-sensitive activity.

Communication

Effective communication is the key to successful delivery of plant materials internationally. Dr Quain actively emails collaborators and holds bi-weekly research team meetings to keep everyone up-to-date on current situations.

Key actions needed for effective communication include:

- Emphasising with the research collaborator the necessity of sending shipment information for live plantlets to CRI so that samples can be tracked while in transit.
- Ensuring international collaborators create sufficient back-up experimental samples so that if samples do not arrive intact, they can be replaced.
- Identifying and contracting a clearing agent is critical to expedite movements through customs. All shipping documentation must be prepared beforehand so the agent can initiate the clearance procedures. The customs invoice for processing charges should be faxed to CRI's accounts office and the amount deposited in an account accessible by the clearing agent. Currently, shipments can be cleared and transported to Kumasi within 2-3 days.
- Clearly labelling packages to indicate that they contain live plants, and marking prominently the temperature at which they should be maintained in transit and whilst in custody in customs.

Lessons

- Communications, labelling and tracking are key to prevent the loss of plantlets, cultures, DNA, enzymes and other fragile materials. Regular communication with research partners is important to ensure that all collaborating partners take proactive responsibility for the safety of the samples and that key information is passed along to all people involved.
- Risk reduction measures addressed are applicable to the movement of all live plant samples, both conventional and genetically modified.
- Awareness of stewardship and specific training of CCP analysis and SOP development needs to be incorporated into the induction and training programmes for all new research staff.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Marian Quain** at marianquain@hotmail.com.*

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Screenhouse plant labelling and product integrity

Stewardship leader:

Dr Marian D Quain

Location:

Council for Scientific and Industrial Research,
Crops Research Institute (CSIR-CRI) – Kumasi, Ghana



CSIR-CRI has a research programme focusing on the application of tissue culture to enhance the production of clean yam planting materials (Quain *et al.* 2011). Yams are a core food crop in the diet of most Ghanaians and the country is a leading yam exporter with 20,841 metric tons exported in 2008 (Ghana Export Promotion 2008). According to the Ministry of Food and Agriculture (MOFA), the annual production of yam in Ghana is approximately 50,000 metric tonnes (MOFA 2008).



During preparation of quarterly status reports on progress of tissue culture research activities for the CSIR in June 2009, Dr Quain examined yam cultures successfully established in September 2008 that were due for rapid multiplication. However, she noticed that the experimental yams were incorrectly labelled with cassava code numbers. After investigation of the mix-up she also discovered that the mother plants in the screenhouse incorrectly bore recycled cassava labels. Marked with non-permanent ink, the labels had faded through continued watering. Young yams (*Dioscorea* sp.) and



Properly labelled yam plants.

cassava (*Mannihot esculenta*) can be confused by merely looking at the plant phenotypes, so labelling is a vital reference check for identification. Dr Quain checked the map of locations of experimental plants in the screenhouse, but the plan could not be relied upon because some plants had been rearranged and there were five different varieties of yam under study. These errors made the results being reported untrustworthy and set the project back several months.

Stewardship

Good stewardship requires precise attention to detail and constant verification of all experimental plant materials. This is critical for responsible new product development. Labels have to be correct as they confirm each specimen's identity. Few staff in the laboratory placed sufficient importance on accurate labelling or understood the need for stewardship. Dr Quain: 'When working with support staff you need to take particular care with how you communicate stewardship needs. Information must be shared in a way that everyone understands and appreciate their role and contribution as diligent research stewards.'



Properly labelled plants by technicians lined up in the greenhouse.



Screenhouse personnel checking the clarity of cassava labels to determine which ones need to be replaced.

The SABIMA training played an integral role in the adjustments the laboratory made to ensure stewardship of accurate labelling. The team reviewed the process for identity preservation using CCP analysis and created a specific SOP for labelling. This now enables staff to track all samples and verify their identity.

To capitalise on this experience and spread stewardship best practices throughout CSIR's Kumasi station, Dr Quain presented a seminar in August 2010 on developing and using CCPs, SOPs and verification strategies to assist in setting research standards and reducing risk of failure in experiments. Following the seminar, researchers requested to have a 2-day training workshop to enable them to put into practice the stewardship principles. To assist in attaining this, two researchers participated in SABIMA stewardship workshop in August 2011 who continued to provide support to Dr Quain in conducting subsequent training.

Challenges

Implementing changes in the working culture of any office or laboratory is not easy, especially when people have been on the job for a long time. Dr Quain faced this challenge when working with screenhouse staff and the transition to using an SOP to ensure accurate labelling.

Dr Quain's approach was to take the time to formally train screenhouse technicians in their responsibilities, including routine tasks such as labelling. For example, if yams are transferred from the field to enable laboratory-based experiments or assessments, employees must check and validate the label and identity of each plant in the screenhouse with the planting map. This ensures that all plants are labelled correctly so that only the right varieties or genotypes enter the laboratory and are used in experiments. Dr Quain made sure everyone in the unit was familiar with one another's responsibilities; this strengthened accountability. Adding more supervision and frequent checks on project status also helped. She used the weekly staff meetings to update everybody on progress. 'Most of the laboratories employ staff with limited formal education. A single mistake can jeopardise an entire team's efforts,' she emphasises. 'So it is crucial that we translate stewardship principles in a clear, understandable and appreciable way.'

Comparing the situation to familiar experiences can help. An example that Dr Quain used for accurate labelling was of addressing other people. 'If you call someone Viv, and her name is

Laura, she will not respond. If you mislabel a plant, giving it another variety's name, you will not get the response you want or expect when the plant grows or is used in research. If you are working with other groups on a project, and they come to collect Viv and you mistakenly give them Laura, not just research time and resources are wasted but also importantly trust and respect is lost between the groups. Being careful on labelling and taking time to recheck is all it takes to prevent these problems.'

Priscilla Boateng, staff scientist at CRI, on an effective way to implement stewardship principles:

When instructions are given to technicians, they are asked to explain their task to the scientist to ensure the message and level of understanding is attained. Although some staff initially felt intimidated by this practice, they understood that it is important for ensuring product integrity and quality. Introducing stewardship has been a gradual process with the technicians since complete changes in ways of working takes time and continued efforts on training and explanation.

Lessons

- Experience has shown that the routine activities that support scientific research are vital for product integrity. Correct labelling of plants during movement from the field into the laboratory is just one example that requires special attention. Others include appropriate labelling when initiating and sub-culturing plants in the laboratory, ensuring legibility and correct labelling when cultures are in the growth room, and checking and ensuring correct labels when cultures or plantlets are being sent to collaborators. An inclusive approach involving all staff members and not just scientists is required for success.
- To set standards that can be maintained, Dr Quain found that training on its own is not sufficient. There also needs to be verification and auditing of staff activities. Suggestions for improvements should be followed up and SOPs should be created or adapted accordingly. Since the yam/cassava incident, Dr Quain has implemented changes so that greenhouse staff thoroughly clean all writing off recycled label tags. Also, strict enforcement and updating of planting maps and supervision of technical assistants during movement of experimental materials has prevented further incidents of plants being mixed up during experiments. There is now greater confidence in the research work being created by the unit and a greater sense of ownership and satisfaction by all the team.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Marian Quain** at marianquain@hotmail.com.*

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Using stewardship approaches to develop improved scientific practices: tsetse fly mass rearing

Stewardship leader:

Dr Alexander Egyir-Yawson

Location:

Radiation Entomology and Pest Management Centre,
Biotechnology and Nuclear Agriculture Research Institute
(BNARI) – Legon, Ghana



Tsetse-borne trypanosomiasis affects cattle and is a severe constraint on the livelihoods of rural communities across 10 million km² of sub-Saharan Africa. African trypanosomes are protozoa that infect both humans (sleeping sickness) and animals and cause annual livestock losses of USD 4.75 billion in potential agricultural production (FAO 2011). In 2008 alone, the World Health Organization estimated that the disease killed 66,000 people (Ferreira *et al.* 2008).

The mass rearing of sterile male insects is critical to controlling these pests and requires the release of over one million sterile males weekly.

The principle of the sterile insect technique (SIT) is that fertile insects are unable to produce normal offspring when they have mated with a sexually sterile partner. Insects can be sterilised by treatment with mutagenic agents (eg, gamma rays, chemosterilants). Such individuals, partially or totally sterile, are released into a native insect population. The greater the ratio of sterile to native insects, the greater the chance of a rapid population suppression. In spite of their genetic aberration, sterile flies usually display the same behavior as their wild counterparts. This is a primary requirement for the success of SIT. Dr Egyir-Yawson's team at BNARI focuses on mass rearing. In 2010, colony numbers started dropping from reduced female fecundity and increased mortality. This was a major problem after the insectary had increased from just 200 pupae to a total of 12,000 actively reproducing females of three different tsetse species in two years.

Dr Egyir-Yawson at the insectary.



Dr Egyir-Yawson noticed unconventional practices such as not checking blood quality for microbial levels (fly feed) when he joined the centre. As mortalities rose, the team had difficulties tracing the source of the contamination in the blood since the blood batches were not tracked. At the time, Dr Egyir-Yawson had no knowledge of the core principles used in stewardship management neither the methods such as CCP analysis and did not know what SOPs entailed. After taking part in the SABIMA training, he

realised the importance of CCPs and SOPs and their benefits to his work and decided to try them out with the insectary.

Communication

There was initial resistance to these concepts and using SOPs. A reaction by technical staff: ‘This is what we have always done, why should we change?’ recalls Dr Egyir-Yawson. An in-house training on principles from the SABIMA workshop helped the team to gradually understand the need for checks and balances to assure quality and success. The presentation also laid out the problem in the insectary and the need to solve it – the team agreed that something must be done.

SOP and CCP development

The discussion was then about how to discover the root issues and use processes to ensure they would not happen again. In the SOP, the whole mass rearing process was streamlined – from blood collection, fly trapping, processing – through brainstorming in group meetings. A mass rearing SOP from an expert in Ethiopia was used as a starting point. The whole team worked on the SOP and CCPs from the onset – this was absolutely critical and each person brought suggestions from their own experiences. Dr Egyir-Yawson stresses that ‘The problem was for everyone so everyone was committed to making a solution. We needed commitment so any decision made would be supported by those doing the work in the insectary.’ This helped to create a real sense of ownership within the team around the creation of the SOP and CCPs.

To create the SOP and the CCPs, ‘The team went step by step through what was done at each stage and what problems could arise,’ explains Dr Egyir-Yawson. For example, the problems with fly mortality had been traced to the blood supply. Blood processing is a key CCP and documentation and tracking systems were put in place to ensure product integrity. When blood is brought in, there is now a form to be filled out on how much blood, where it is from, how it is treated, what are the microbial levels, and what is the batch number. All blood is labelled by batch so it can be tracked through the system should contamination be detected. The form moves with the blood batch through quality testing, irradiation, and on to the insectary where all withdrawals are recorded.

Stewardship

Dr Egyir-Yawson attributes the newly implemented SOP and CCPs as ‘critical to getting the mass rearing program back on track.’ When asked to attend the SABIMA training, he recalls, ‘I did not expect it to directly benefit the insectary since it was about plant biotechnology, not animals.’ But he quickly realised that the stewardship principles were applicable to the problems he was faced with in his own lab. Material from the SABIMA

Insectary staff measure a new batch of blood into labeled containers for analysis and tracking.



training was used to train the mass rearing team on the product lifecycle – translated from plants to flies – to make it directly applicable.

The director of the institute is now calling for SABIMA training for the whole institute after seeing the results and impact it has had on the outputs of the mass rearing team.



Blood is tested and tracked through the system. Such tracking has already lead to significant savings from tests showing bad blood prior to it being fed to the flies. Staff are now excited and committed to the stewardship practices.

Challenges

Resistance from the technical staff on the need to do things differently was an immediate challenge. Dr Egyir-Yawson explains: ‘The team was not too happy about the SOP since they thought it would be too stringent and involve strict monitoring. As the boss, I had to insist on setting consistent standards within the team. Good science must be repeatable and dependable.’

With the SOP and CCPs in place, the staff realised they would have lost many more flies without the SOP-indicated testing of the blood, since a recent batch had overly high microbial levels. The team is quite proud of the SOP and insisted on sharing copies with the visitors from the national service. The SOP was also included in the annual report giving the staff recognition for their work and also points for promotion.

The actual writing of the SOP and CCPs took a long time, about 8 months from start to implementation. The slides from the SABIMA training helped, as well as talking with other scientists, but more frequent consultation from a more structured advisory program after the SABIMA training would have made the process much quicker and less frustrating. For Dr Egyir-Yawson, ‘It was not so much the specific information for the SOP that was difficult; it was the actual process of writing SOPs and CCPs for the first time.’

Lessons

- ‘Stewardship principles are useful for any organisation involved in the development or production of any product,’ explains Dr Egyir-Yawson. It is just a matter of tailoring the components in the stewardship and quality management systems to address the type and scope of the particular institution’s activities relative to its product life cycle.
- ‘Building project ownership and involving each team member was probably the most important way to break down resistance,’ shares Dr Egyir-Yawson. This transformed the insect rearing from just routine work to each person actually feeling responsible – making a huge difference. Developing the SOPs and CCPs helped create a whole team mentality,

since each member's input was so valuable in determining what could be problematic at each stage of the process. After the initial draft, Dr Egyir-Yawson worked on putting final touches on the SOP and was told by the team that he was taking too long; they wanted to start using it right away!

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Alexander Egyir-Yawson** at egyiryawson@hotmail.com.*

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Case Studies: Kenya

Management of gene flow in transgenic sorghum in contained biosafety greenhouse trials

Stewardship Leader:

Dr Joel Mutisya

Location:

Kenya Agricultural Research Institute
(KARI) – Nairobi, Kenya



Sorghum is the second most important staple food crop in Kenya. Per capita sorghum consumption in Kenya is approximately 3.0 kg per year (FAO 2002) and it is able to endure increasingly frequent droughts far better than maize (Omanya *et al.* 1996). Ancestrally from Africa, sorghum has many traditional foods uses, making it the target of new biofortification research on improving

levels of required nutrients – vitamins, iron and zinc. To make an impact on dietary needs, high expression levels must be achieved. Since conventional techniques have failed to reach these levels, genetic modification is necessary.

Dr Mutisya explains, ‘Since sorghum has wild relatives in Kenya, preventing pollen escape from the greenhouse is critical to prevent gene flow. Greenhouse trials are done in sorghum-growing regions, and so particular vigilance is required to prevent any unauthorised environmental release prior to governmental approval.’ Containment

regulation stipulates that a double door is required at the entrance of the Level 2 Biosafety Greenhouse to contain the pollen. Dr Mutisya and his team were concerned that pollen could still escape on clothing or shoes. To be good stewards of the technology, the team sought more thorough solutions.

The team started by thoroughly examining the biology of sorghum, especially with respect to pollen. Through investigation of the growth and development of sorghum; when and how flowering occurs; pollen production; and its timing, spread, longevity and ways of causing pollen mortality enabled Dr Mutisya to create the following experimental course of action. In the 30 days between flowering and stalk death, huge amounts of pollen are produced and dispersed, mostly in the early afternoon. To combat this dispersal during experiments, the flowering sorghum head is covered with a pollination bag. Any pollen that escapes falls to the floor. The greenhouse staff thoroughly douse the floors with water every morning and afternoon and any pollen is washed into a disposal tank. This contact with water kills the pollen and prevents any cross-fertilisation with other plants. 'Because of the extra precautions taken,' says Dr Mutisya, 'we went beyond regulatory requirements and are very confident that we are preventing viable pollen from escaping from our research facilities.' This containment is important for environmental reasons and also for the reputation of the research unit. Responsible and rigorous scientific methods will build governmental and public confidence in the work and in the ability of the scientists to undertake safe development of new beneficial technologies to improve food security for the Kenyan people.

Stewardship

The SABIMA training sensitised the team to using stewardship methods to think proactively. CCP analysis enabled the team to identify key areas where problems could arise and pre-emptively create action plans to cope with incidents. Dr Mutisya explains, 'We learned to think ahead and to plan strategies to avoid incidents, like pollen escape from the experimental facilities. Pollen can get on your clothes and easily be transferred to other plants in our institution or outside.' Now, scientists and technicians wear special long laboratory coats and have adopted a specific regime for washing hands to prevent inadvertent pollen transfer.



Dr Mutisya examining sorghum plants at the KARI Level 2 Biosafety Greenhouse.

Greenhouse floor being doused with water to kill pollen grains.





KARI scientists and management outside the biosafety greenhouse for SABIMA training

The sorghum trials followed the existing *Bt* maize greenhouse trial SOP, but include new CCPs and methods for pollen control. Dr Mutisya's team, as the lead African institution on the project, is developing a complete set of sorghum SOPs, covering aspects such as CFTs, record keeping on data collection and transportation of transgenic materials. With Nigeria and Burkina Faso conducting trials in the future, they will learn from Kenya's experiences and modify the SOP to fit their exact situation.

Communication

For the new approach on pollen removal to be successful, it had to be communicated, accepted, implemented and become part of the normal working practices of greenhouse staff. Staff were told what needed to be done and why it was so important, and for it to be seen as an important responsibility for all involved and not just a new routine task. Dr Mutisya says, 'I believe the change was seen as a positive development because staff had received previous training on greenhouse biosafety that included discussions on the importance of precautions, action plans and problem resolution.'

Lessons

- Dr Mutisya encourages scientists and technical staff to 'Share experiences and profit from the thinking and best practices established by colleagues. The solution we found could be valuable to other researchers, especially those working in similar areas or in multi-country projects. It is so much better to learn from others before you have a problem or have to manage a major incident resulting from insufficient foresight or scientific rigour.'

- In the case of prevention of pollen flow, explains Dr Mutisya, ‘Each crop is unique. Understanding the biology of a crop is paramount in developing a tailored stewardship plan. CCPs need to be assessed and tailored for each crop, and then adapted, developed and implemented in each research facility to be fully effective.’
- Implementation of new safety methods and ensuring that they are always adhered to requires full involvement of the staff and their ownership. This needs time for training and consultation; both are essential if changes are to be part of normal work routines and high standards are to be kept.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Joel Mutisya** at jmjoel2002@yahoo.com.*

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Multi-county project cooperation on hardening transgenic tissue culture cassava plantlets

Stewardship leader:

Dr Douglas Miano

Location:

Kenya Agricultural Research Institute (KARI) - Kakamega, Kenya



Cassava is a major food security crop in western Kenya (Mbwaka 2000). It is also an important crop throughout the country due to its ability to survive in drought conditions (Nweke *et al.* 2002). With severe dry spells becoming more frequent, maize is suffering and drought-tolerant 'orphan' crops like cassava, sorghum and sweet potato are receiving more research attention. Two joint cassava projects are being undertaken in Kenya – biofortification with Nigeria and virus resistance with Uganda – both led by the Donald Danforth Plant Science Center (DDPSC), USA.

For both projects, DDPSC ships transformed tissue culture plantlets to project countries for CFT evaluation. The transformed tissue culture plantlets are very tender and cannot be moved directly from lab to field, a step Dr Miano identified as a CCP that needed a special SOP. 'To make the plantlets strong enough to deal with harsh conditions outside, they must be hardened in the greenhouse. This enables them acclimatise to field conditions, develop strong roots, and adapt to lower humidity levels,' explains Dr Miano.

The project partner organisations, Uganda's National Agricultural Research Organization and Nigeria's National Root Crops Research Institute, quickly encountered issues in the hardening phase. Nigeria faced losses from cassava bacterial blight and Uganda from very weak plantlets. Dr Miano explains: 'The incidences in Nigeria and Uganda prompted us to think about the

KARI cassava scientists examining a plantlet shipment from DDPSC.



challenges that we may encounter during the hardening process and the importance of learning from others.' The Kenya team tested the current SOP with conventional plantlets as a measure to anticipate any practical problems before using transgenic plantlets. 'The goal was to develop an in-country hardening process with a high success rate, using affordable, locally available materials,' says Dr Miano.

In the first dry run, half the plantlets were lost to fungal infection – different from Nigeria and Uganda's experiences. Fungal contamination was a potential stewardship problem beyond just the cassava project. All tissue cultural plantlets must pass through a similar hardening process, including the



Newly received plantlet ready for hardening in the greenhouse.

disease-free plantlets KARI produces. If the fungal infection could not be resolved, according to regulations, none of the infected plantlets could leave the greenhouse, bringing the project to a halt and requiring all the materials to be destroyed. The team did additional dry runs to trace the source, identifying transportation of vermiculite to the field stations as the source of the fungal contamination. All vermiculite is now sterilised via autoclave, solving the CCP.

To develop their SOP, the team discussed the situation with Dr Titus Alicai, Uganda's principle investigator for the cassava project about successful processes in Uganda's programme. The sharing of insights and experiences was critical to not repeating mistakes and for creating the best solution. The Kenya CCP/SOP team included personnel at all stages in the project – from the greenhouse manager and tissue culture scientists to greenhouse staff. Since the greenhouse staff do most of the implementation of the CCPs and SOP, it is critical that they fully understand and own the process. By having them contribute and prepare the document, they are sure to follow all the steps and easily identify steps that could be improved.

Stewardship

The SABIMA training sensitised the scientists to formal SOPs and the analytical process of identifying CCPs. When the first diagnostic dry run was done, the CCP aspect of SABIMA had not been taught, so as soon as that module occurred, the scientists used the training to analyse every possible step in the processes that could result in contamination. All the plant growing components – soil mixtures, vermiculite, pots, water, fertilizers – were separately evaluated. The vermiculite proved to be the common thread among all the contamination and was previously not sterilised before use. Now, before a large trial is run, a few plants are potted and checked after 3 days to ensure no infection has occurred. This additional verification step is part of the SOP developed around the contamination CCP.



Dr Miano examining cassava plants in a KARI screenhouse.

SABIMA's main impact was to make it clear that product development is more than just following specific regulatory rules. It is also about having confidence in the final product by evaluating each aspect in the process. Dr Miano commented that thorough record keeping, to the extent that everything can be tracked at a given time, is still a challenge. But now with an understanding of stewardship and what success looks like, the team is able to objectively evaluate the areas in their program that need improvement and take steps to change.

Dr Miano: 'Understanding and implementing stewardship practices into scientific programmes allows everyone to feel confident – the scientist, the donors, and the eventual consumers.' The main interna-

tional partner for the transgenic cassava project, DDPSC, was very supportive of the stewardship training since it created confidence in the product development, regulatory and eventual commercialisation. DDPSC is considering implementing similar training for all their projects.

Lessons

- Whenever possible, test a process by doing a dry run before the actual experiment.
- 'It is wise to communicate and consult with others who have done similar work, learning from their experiences. In hearing about what they have seen, CCPs can be identified. Knowing the places to be cautious can save time and prevent issues,' explains Dr Miano.
- Developing accurate and thorough best practice SOPs allows communication between partners in a straightforward, scientific way. They enable step-by-step comparisons between approaches to areas where SOPs differ.
- 'Stewardship has made me expand my thinking beyond today to the whole process and how our work will be viewed in 10 years. Stewardship also covers safety beyond regulatory requirements and speaks to the moral environmental aspects that we can address through careful control of all our processes,' says Dr Miano.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Douglas Miano** at dwatuku@yahoo.com.*

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Preparations and running mock confined field trials

Stewardship leader:

Dr Joyce Malinga

Location:

Kenya Agricultural Research Institute (KARI) – Nairobi, Kenya



Cassava is an important dry-season root crop that copes with drought far better than maize. It is consumed year round in many regions of Kenya and is produced on over 70,000 hectares, with production over 800,000 tonnes yearly (FAOSTAT 2011). While cassava delivers necessary calories, it lacks important micronutrients like vitamin A and iron, resulting in severe deficiencies. In Kenya, it is estimated that 23,500 child deaths annually are directly linked to micronutrient malnutrition and that 70% of the children under age six have subclinical vitamin A deficiency (Micronutrient Initiative and UNICEF 2005). Approximately 30% of Kenyan preschool children also are vitamin A deficient, in addition to suffering from inadequate iron and protein. There are local landrace varieties containing beta-carotene, the precursor to vitamin A, but it is not bioavailable to humans. Much effort has gone into trying to increase beta-carotene levels using conventional methods but none have been successful.



The difficulty of cassava breeding is the greatest challenge; it is not simple like with seed crops (maize) since the cassava seed coat is extremely hard, requiring harsh chemical treatment to break down so the seed can germinate. Pollination does not occur easily; the pollen is heavy and can only be transported about 30m by wasps (Hasley *et al.* 2008).

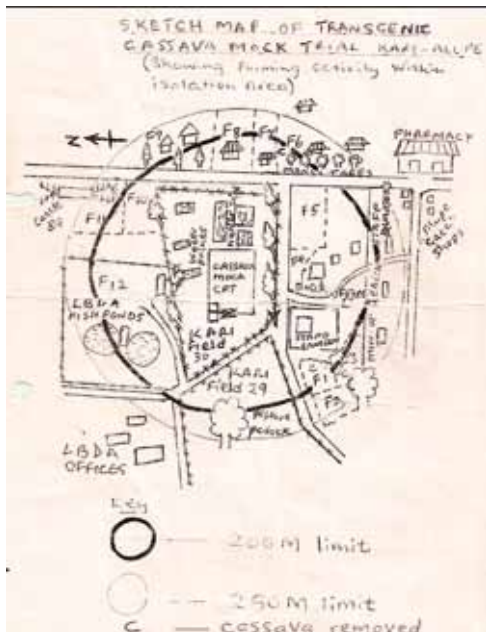
The Virus Resistant Cassava project (VIRCA) decided a mock confined field trial (CFT) was necessary for scientists and technicians to gain experience handling genetically modified (GM) plants and to ensure that the proposed procedures ran smoothly. The mock CFT was set up and run in 2004 exactly as a GM trial would have been conducted, but only conventional plants were used. Tissue culture plantlets were shipped from the US, picked up at the airport, hardened in a biosafety greenhouse, transported to the prepared field, harvested and incinerated. The mock CFT ran for 18 months – 12 months *in situ* for the actual trial with daily collection of data, and six months for post-harvest monitoring to ensure any volunteer plants were destroyed.

Mock cassava CFT entry gate.



Points of learning

The mock trial enabled the cassava team to anticipate potential problems and weak-



Diagrammatic demonstration of isolation distances from the 2006 mock trial report.

are more than enough to prevent gene flow. While members of the CFT team felt the 100m distance should be used, Dr Malunga held firm that the dossier must be followed to the letter and that for future trials they could submit the recent research to the biosafety committee for reassessment of the isolation distance.

Mock CFT staff with KEPHIS officer and VIRCA partners. 50% of staff were retained for the GM CFT, with several becoming trial managers for related GM cassava trials.



nesses in the protocol that could lead to lack of data generation, loss of plants and, most importantly, potential biosafety breaches, and to experiment with solutions in a low-risk environment. In Kenya, a biosafety breach can result in prison and USD 250,000 fine for those responsible, as well as cancellation of the CFT. One potential breach was farmers growing cassava within the 200m isolation distance as stipulated in the regulatory dossier. Though farmers were compensated for not planting cassava, some did not uproot cassava plants until forced to do so. For the GM CFT, the monitoring team was more active about checking fields and visiting farmers, village elders, and local institutions about the importance of not planting in the isolation zone. The 200m distance was based on current research when the dossier was submitted, though more recent research has conclusively demonstrated that 100m

Poor maintenance of entry and exit records of technical staff proved a problem in the mock trial. They either forgot to sign in or brought friends. In the real CFT, it has been stressed that visitors must have authorisation from the trial manager. It is a matter of record keeping, having records of everyone who comes in and out in case there is a problem with the trial.

The mock trial was invaluable to anticipate practical aspects of the approved protocol to deliver full compliance and also to consider factors such as operational capacity and staff know-how. The mock trial was completed in 2005 and the first GM cassava field trial at KARI, launched in May 2011, is set to run through November 2012 (a 12-month growing season and 6 months for post-harvest monitoring). A key learning point was that there is an optimum time to conduct the mock trial. It needs to be conducted within sufficient time for the learnings to be internalised and for the SOPs and CCPs to be created, but not too far in advance of the planned GM CFT – no more than 18 months beforehand. If any longer, as was the case with the cassava CFT, people tend to forget their training or leave for other jobs. Several follow-up trainings should be done with the CFT staff prior to the trial for practice so that everyone is confident with their roles. Dr Malinga suggests that just prior to the GM CFT, a mini dry run be done in a small section on the side of the actual CFT area just before planting the GM trial. This will allow for continued practice and for the SOP to be kept in mind.

Challenges

One of the main intentions of the mock trial was to determine the time and staff requirements necessary to run an 18-month operation. For cassava, it was critical that the plants never flower to eliminate potential gene flow. Technicians need to manually remove new flowers each day and make other data observations. Keeping technicians motivated to ensure quality of data collection in their day-to-day routine proved challenging. In the mock trial, post-harvest monitoring was continued for 6 months to ensure there were no volunteer plants. This period was too long to maintain technicians, greatly adding to the cost of the trial.

Dr Malinga suggests: ‘They should have done a crop rotation programme, with a leguminous green manure crop allowing the ground to recover its nutrients and for any volunteers to grow within 2 months. The two months would have been sufficient for cassava.’

One key for success was having a postgraduate student oversee the day-to-day operations of the mock CFT. Since the student was writing a paper on the trial and required high-quality data, his attention and personal involvement with them helped to motivate the technicians to gather the correct data and to adhere to stewardship principles. Other scientists wrote on the flora and fauna occurring at Alupe (Lukhoba 2006, Mulaa *et al.* 2006). Paying the technicians competitive wages also helped. The subsequent paper also enabled the team to share the process and learning of the mock CFT with project partners and others through presentation at the African Crop Science Conference (Mallowa *et al.* 2008, Mallowa 2006).

Stewardship

Mock trials present the opportunity to identify CCPs and to fine tune SOPs. While at the time of the mock CFT, the team had not yet had SABIMA training on formally creating SOPs and CCPs,



Cassava plants being hardened in the KARI Kakamega greenhouse prior to transplant in the CFT.

through SABIMA they were able to draw on the mock trial experiences and generate documents to guide the GM CFT. For the identification of CCPs, direct involvement of field technicians doing the day-to-day operations proved invaluable. When CCPs were identified, the team could investigate which options were best to verify and resolve any subsequent problems. For example, completely destroying cassava plants is critical for preventing unintended product release. As this proved challenging, a technician came up with the idea of chopping the plant matter and drying it, making incineration possible. Such problem solving is possible in this low-risk, learning environment of a mock CFT using only conventional plants.

To ensure the required number of plants reach maturity in the CFT, a CCP was identified to ensure that sufficient plants were available. Explains Dr Malinga, 'There is not a 100% survival rate from shipping to hardening to field and the CFT enabled scientists to determine the percentage of plants that died in the pre-planting process.' By the time the GM CFT began, enough extra plants were available.

Accurate and diligent record keeping is critical, and during the mock trial the team devised a method to label each plant with a unique tag for individual data collection. During analysis it was made clear that tags must not fall off or become mixed up. A physical layout diagram with each plant's location helped to alert in case of a mix-up.

Dr Malinga: 'SABIMA has completely transformed the way I view the regulatory process as a help rather than an impediment. I've gone out of my way to train undergraduates and my lab staff about stewardship as a personal initiative. While following regulations is critical, a bit of extra personal regulation and stewardship leads to a successful study and final product.'

Stewardship leads to more confidence in the work by government officials and research partners, while ensuring the environment is respected and enhancing the overall quality of work. Impressed with the training results and understanding the importance of stewardship, the main donor for the project, the Donald Danforth Plant Science Center, contracted the SABIMA stewardship trainer to undertake stewardship trainings for scientists on the Bio-cassava Plus project.

The key contribution of stewardship training was around self-regulation and regulatory compliance. Stewardship understanding enabled the team to plan out the SOPs, critically predicting possible CCPs that could result in non-compliance and poor data quality. Any possible breaches in regulatory compliance were avoided through careful planning from the beginning of the project, as well as from running the mock trial.

Communication

For staff and technicians, hands-on workshops were conducted on biosafety, CFT management, and the value of stewardship. These workshops showed both the benefits of the research and the serious penalties for non-compliance. It became clear staff also required communication training since, as Dr Malinga says, ‘Staff did not know what message to give about the trial so it would be well received by the local community and not perceived negatively.’

A simple one-pager was created and distributed to local public officers and opinion leaders who visited the CFT, providing confidence from the stewardship implementation, and demonstrating that actions beyond regulatory requirements were being undertaken. The team learned that the one-pagers should not be overly scientific – they had to relate to day-to-day aspects that people know and can relate to. More emphasis should be placed on the need for the trial in terms of human health and agricultural benefits without overly focusing on the more scientific aspects of genetics and biotechnology.

Lessons

- Dr Malinga: ‘By taking the lessons from this case, countries could run a CFT for 6 months instead of 12-18 months and still gain the important operational experience for all aspects of the protocol and generate the essential scientific data needed.’ The exact time period depends on the crop: 3-4 months to simulate an early-maturing maize trial; 4-6 months for cassava or sweet potato trials. The same variety need not be used for the mock and GM trials.
- Dr Malinga recommends using the mock CFT as an invaluable stewardship approach and encourages other countries to take the model Kenya has developed, optimising and customising it to their own resources and needs.

Acknowledgements

Dr Malinga would like to thank Danforth Plant Science Centre for partnering with KARI through the long process to reach the transgenic CFTs, and USAID for funding the mock CFT. She would

also like to thank KARI for trying out the new innovations and the team at KARI Kakamega, especially Sally Mallowa, who left before she could see the real CFT, and Simon Gichuki, who still leads the team.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Joyce Malinga** at joycemalinga@yahoo.com.*

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Case Studies: Malawi

Tracking certified seed product integrity from contract production to grower

Stewardship Leader:

Mrs Grace Kaudzu

Location:

Department of Agricultural Research Services (DARS),
Seed Services Unit (SSU), Chitedze Research Station –
Lilongwe, Malawi



With Malawi's population growing at 2.8% annually (National Statistical Office 2008), increases in agricultural productivity are necessary to ensure food security and sustainable growth. Availability and use of agricultural technologies, such as high quality, certified conventional seed, is a step towards achieving increased production. With farmers realising the benefits of certified hybrid seed, such as yield increases over 20% (Chibwana *et al.* 2011) and predictable germination rates, adoption has rapidly increased from 10 to 43% over the past decade (Seed Trade Association of Malawi 2010).



Seed certification and quality control activities to ensure that only quality seed is offered for sale have been developed and implemented by Seed Services Unit (SSU) at the Chitedze Research Station. Product integrity is a key stewardship principle and SSU works to maintain this through monitoring activities of seed producer and seed from



A field of hybrid certified maize seed, monitored closely by SSU. Note the empty row where male pollen plants were growing, removed to prevent mixing during harvest.

Evaluating germination rates of certified hybrid seed grown by contract farmers in the lab at the SSU.



registration, production, harvest, processing, final certification and market sale. With increasing prevalence of fake certified seed on the market, Mrs Kaudzu and her team identified points along the certified seed value chain where standards could be checked at CCPs to address this challenging problem. Each step in the process was analysed for activities where product integrity could be compromised, and verification or control measures were then established.

Stewardship

Product stewardship is central to ensuring only high-quality certified seed reaches the market. Mrs Kaudzu explains: ‘The SABIMA training increased my knowledge and ability to find the best ways to prevent, reduce or eliminate negative effects on a product throughout its life cycle. Identifying CCPs is very important to systematically and formally understand the points where unacceptable activities can happen, leading to compromised quality of seed in our programs.’

The training also emphasised the importance of developing and following SOPs that reflect the identified CCPs. Mrs Kaudzu was encouraged by SABIMA to set clear and consistent standards, with no exceptions permitted for seed producers, because anything less than strict adherence to the SOPs could compromise product integrity.

Critical control points (CCPs)

The following examples and response methods are applicable to not only to certified seed production, but also for tracking the integrity of all seed produced.

Isolation. Cross pollination can occur between outside maize plants and the certified maize

hybrid seed in production, compromising product integrity. A 400m isolation distance from any other maize is required, but can be reduced if border rows are planted. Also, time isolation through differential sowing dates may be permitted (flowering dates must differ by at least 28 days to completely prevent pollen flow).

Field inspection. Field inspections facilitate the removal of off-types (plants or seeds that deviate in one or more attributes from the breeder's description) from the seed crop field that would also compromise product integrity. Field visits during critical stages of crop growth – pre-flowering, flowering and post-flowering stages – are critical to identifying off-types.

Production volumes. With certified seed fetching more than 50% higher prices than commercial seed, some farmers attempt to mix non-certified seed with their certified production to increase the volume. As a CCP, several steps were developed to combat this practice. The field inspector visits the grower at least five times throughout the season and estimates yield based on crop performance. SSU uses this yield projection as a check. If the farmer brings considerably more seed for processing, it is a red flag that the farmer may have illegally mixed seed. Mixing can also be discovered during laboratory seed testing because in most cases the two lots mixed are not the same variety and the grains may look different in terms of shape, size, colour or flintiness. To further ensure product integrity, SSU would like to develop capacity in molecular analysis to verify seed purity at the molecular level.

Labelling. Consumers can be misled into buying fake seeds at an open market that bears a company's brand name. Proper labelling can help consumers select seed that is certified. SSU stipulates that all certified seed must have an official label which includes name and address of the supplier, kind and variety of seed, class of seed, date of testing and the lot number. The lot number, given to a grower when they initially register with SSU, is key for tracking the seed from the grower through the entire value chain. SSU actively monitors seed selling points, like agro-dealerships and open markets, verifying seed is labeled correctly and that the seed producer was registered as a contract grower for a registered certified seed company.

Challenges

Implementation and continued use of the SOPs by the farmers proved challenging, especially when farmers tried to use shortcuts such as unsatisfactory isolation distances, poor land history (growing same crop for two consecutive seasons), poor grading of seed, mixing of certified seed with non-certified seed, and poor seed handling and storage. If a farmer did violate the SOP and took shortcuts, thereby compromising product integrity, the production field or seed lot was rejected by SSU.

To reduce the number of farmers taking shortcuts, and to ensure high quality seed production, SSU conducts formal and informal trainings with all farmers on seed certification and quality control. Formal trainings are organised every year, with seed producers trained on seed production SOPs before the season starts. Informal trainings are also provided to individuals who come to SSU and show interest in seed production. At the training, the opportunity exists for farmers to register to become certified seed producers. Farmers are given copies of the

SOPs to implement in their fields. Because of these trainings and guidelines, there have been fewer rejections and stronger production of high-quality seed.

Mrs Kaudzu believes there ‘should be more stewardship training for seed producers and seed inspectors because the SABIMA stewardship training provides exactly what is needed to support seed certification and quality control. It would help inspectors to understand and put in practice more stewardship principles to ensure product integrity.’ One week-long training session could be conducted each year, covering introduction to stewardship, incident response, and verification and audits.

Lessons

- Stewardship training is a vital ingredient for excellent management of seed production, seed certification, and quality control.
- Regular reviews of all the processes in seed programmes are needed together with quality assurance measures such as training for seed producers in SOPs. But training alone on SOPs by seed producers is not enough. The financial rewards from selling certified seed are too great, so a thorough understanding of points in the value chain and production pathway where misunderstandings, adulteration, misrepresentation or shortcuts can be made is vital. To maintain seed quality and ensure product integrity, special focus is needed on SOPs for seed production, processing, labelling, transportation, storage, and tracking of the seed lots. Quality control checks must be done at these CCPs.
- Often stewardship is considered as a process used primarily for biotechnology crop research and development, but Mrs Kaudzu has found that this way of thinking and using core methodologies such as CCP analysis can greatly assist in her mission to ensure that quality, dependable, certified and conventional seed reaches farmers.

*For more information on the experiences and stewardship principles covered in this case, please contact **Mrs Grace Kaudzu** at gkaudzu@gmail.com.*

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Case Studies: Nigeria

Ensuring purity and integrity of Bt cowpea seeds through effective labelling and record keeping

Stewardship leader:

Dr Mohammad F Ishiyaku

Location:

Institute for Agricultural Research (IAR),
Ahmadu Bello University - Zaria, Nigeria



Cowpea is the most important food legume in Nigeria, providing both a cash and a subsistence crop for farmers throughout the country (Langyintuo & Lowenberg-DeBoer 2003). Nigeria produces 2.5 million metric tons annually, but has a 0.5 million ton deficit – largely from *Maruca* stem borer pressure (Ishiyaku 2009).



So far, research on natural resistance through conventional breeding has remained unsuccessful (Singh 2002) and an alternative approach is now being explored using genetic modification to insert the *Bt* gene, enabling the plant to produce a toxin that is lethal to target insects. The *Bt* cowpea project is supported by Commonwealth Scientific and Industrial Research Organization (CSIRO) in Australia, the African Agricultural Technology Foundation (AATF) in Kenya, the Network for Genetic Improvement of Cowpea in Africa (NGICA), the Environmental and Agricultural Research Institute (INERA) in Burkina Faso, and the Savannah Agricultural Research

Institute (CSIR-SARI) in Ghana. As part of this project, IAR performed a *Bt* cowpea CFT in March 2009 in Nigeria.

Maintaining the *Bt* cowpea product integrity – every seed expressing the expected characteristics – and safe stewardship entailed ensuring that different seed lots were not mixed, experimental seeds were not lost, and unintended environmental release did not occur.

Dr Ishiyaku explains: ‘It required close planning and implementation of stewardship principles on seed packaging, labelling, record keeping, and tracking from receiving experimental seeds, through storage of seeds on completion.’ To ensure product integrity, CCPs were identified through the research process. CCPs included:

1. Shipping methods of *Bt* cowpea seeds
2. Receipt of shipment of *Bt* cowpea seeds from Australia
3. Storage of *Bt* cowpea seeds upon arrival in Nigeria
4. Transport from storage to planting field
5. Planting the field trial

Mistakes at any of these five steps can compromise the quality of the final *Bt* cowpea materials.

When transgenic seed packets arrived from CSIRO, all were closely examined by regulators and scientists to ensure that they had not been disrupted and that the contents were as expected. Diligent records were kept on the number of seeds received in each packet (recounted to verify), total number of packets (with their ID numbers), and all genotypic/variety information on each labeled packet. These records were compared against the list of materials emailed from Australia. Such labelling and records also enabled the scientists to track the seed and packets through the system – transportation from seed storage, planting in the field, harvest and storage of second generation seeds.

When planting started, Dr Ishiyaku’s team recorded the number of seeds removed from each packet at the storage facility to be taken to the field and the number of seeds remaining. The seed storage facility for *Bt* cowpea was securely locked, with only Dr Ishiyaku and the trial manager having access. Each had to record time entered and exited as well as seed data. Upon reaching the field, seed was recounted before planting according to experimental design and planting was supervised by the lead scientist.

Harvesting is a critical time to manage product integrity, especially since *Bt* cowpeas are physically indistinguishable from conventional cowpeas. The lead scientist oversaw all harvest and trashing, ensuring all safety measures were followed. Harvest bags were laid on each plot and labeled inside and outside. The *Bt* cowpea bags were new, red, double-thick cloth with red



*IAR scientists receiving the *Bt* cowpea seeds from Australia. An important CCP was to compare the shipments contents with what was reported and expected.*

ink labels and the conventional cowpeas used white bags with black label. Labels were verified to make sure the bags matched the plots and contained all the necessary information on plot number, replication number and genotype. Only harvested pods from each plot were put in their respective bags, and then the tops were securely tied with a strap to prevent any pods or seed from falling out.

Trashing was done by hand, plot by plot. All shelled seed was put into the appropriate bag before the next plot was started. The yield was about 2kg seed per plot, with number of pods, number of grains, and total weight recorded in the field logbook. When the bags reached the lab and secure storage facility, records were also made.

Challenges

‘The main challenge was negative perception associated with having the *Bt* seeds in red bags,’ explains Dr Ishiyaku. People outside the project thought the red indicated contents that required special attention and implied risk. To neutralise this perception, the team now uses green bags and labels for *Bt* cowpea.

Stewardship

‘When the *Bt* cowpea trials started in 2009,’ recalls Dr Ishiyaku, ‘someone mentioned stewardship, but no one knew what it meant. SOPs were also mentioned, but we did not know their value and thought they were too complicated to create.’ Prior to the training, Dr Ishiyaku explains that he was ‘...consumed by the regulatory compliance and did not think beyond what was required by the Nigerian regulatory authorities.’ With the SABIMA training, he realised the importance of doing more than the requirements in terms of formalising best practices around packaging, labelling, records and tracking to adequately maintain integrity of output.



Original Bt cowpea research seed bags.

A key analytical method advocated in the SABIMA training was evaluating CCPs and creating tailored SOPs to reduce the risk of loss of product integrity. The *Bt* cowpea team has actively assessed the CCPs along the entire chain of enabling activities to CFTs on cowpeas, including harvesting and post-harvest tracking of seeds, and has formalised best practices into SOPs. Details around proper labelling, packaging and record keeping have been given special attention, as they are key contributors to product integrity.

The various CCPs were identified as a result of the outcome of analyses of several scenarios that might lead to loss of or mixing of the *Bt* and non-*Bt* seeds. If product integrity is compromised,



*Scientists lay out Bt cowpea planning materials.
Dr Ishiyaku identified this step as a CCP.*

consequences include loss of confidence in the scientific team by stakeholders along with extensive political and legal liabilities.

Dr Ishiyaku, recognising the value of evaluating CCPs and creating SOPs, says 'With formalised procedures and meticulous records, all processes can be repeated, even when the head scientist is absent.' Also, when new staff arrive they use the SOP to gain an understanding of operations and require less additional instruction, adding to the ease of operation.

The developed CCPs and SOPs are being shared with IAR colleagues working on sorghum, enabling them to learn from Dr Ishiyaku's experiences and attention to stewardship.

Lessons

- Due to the implemented stewardship practices, donors and partners are more confident in Nigeria's work on *Bt* cowpea. 'USAID conducted a formal audit of the project in 2010, and was very satisfied with their findings. Our detailed documentation methods have built trust among not only our colleagues, but also IAR's external *Bt* cowpea development partners,' explains Dr Ishiyaku. The stewardship programme has also opened the way for more collaboration with seed companies planning to invest in Nigeria.
- Dr Ishiyaku emphasises the importance of verification and '...looking back over each stage to double check that the process carried out was done correctly, never take any chances when ensuring product integrity and regulatory compliance.' The SABIMA training, which encourages this rigorous approach, led Dr Ishiyaku to verify that received seeds contained the specific gene construct of interest. Initially, molecular verification was not possible due to lack of scientific capacity at IAR, but now he has implemented polymerase chain reaction (PCR) verification along with the dipstick method, where specific colour change indicates the presence or absence of the gene product
- Training technicians is key for convincing them that mixing of seed is not allowed and separate genotypes and seeds from different trials must be maintained in the appropriate packets. While this is also emphasised in conventional breeding programmes, it is vital when working with GMOs.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Mohammad Ishiyaku** at mffaguji@hotmail.com.*

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Case Studies: Burkina Faso

Conducting Bt cotton controlled release field trials with farmers in Burkina Faso

Stewardship leaders:

Dr Hamidou Traoré (right) and Mr Omer Héma (left)

Location: Institute for Environment and Agricultural Research (INERA) – Ouagadougou, Burkina Faso



Agriculture in Burkina Faso accounts for 37 % of gross domestic product (GDP) with cotton as the main cash crop, supporting 2 million farmers (INERA 2002). High insect pest pressures from *Helicoverpa*



armigera, *Diparopsis* sp. and *Earias* sp. cause 50-70% reductions in quality and yield of the bolls, leading to more frequent pesticide use (Hema *et al.* 2009). Exploring alternative solutions, the government, INERA and Monsanto started controlled experiments in 2003 with insect-resistant *Bt* cotton, containing a gene for the production of the Cry toxin, lethal to some insects. Testing was done at three research stations: Farako-Bâ in the west, Saria in the centre and Kouaré in the east. In 2008, *Bt* cotton was commercially released to farmers. A key stage during this seed development programme was the transition from conducting highly controlled research trials to evaluating *Bt* cotton for insect resistance on a larger scale by commercial farmers.

All agronomic advancements conducted by INERA need pre-extension testing before release to verify real benefits for commercial farmers. In 2007, after the *Bt* cotton had successfully completed confined field trials (CFTs) at research stations, 20 farmers from across Burkina Faso enrolled in pre-extension tests in CFT conditions.

The participating farmers were chosen in collaboration between INERA and the cotton company extension services from a group of volunteers known to be innovative and ready to implement INERA recommendations. Because the fields also served as demonstration plots, the participating farmers were asked to receive visits from other farmers – an arrangement that most participants accepted with considerable pride.

Each farmer grew 0.5 ha of *Bt* cotton next to an equivalent area of conventional cotton. Prior to planting, farmers were trained by the INERA scientists on the importance of environmental safety and maintaining product integrity. The prevention of gene flow by pollen was managed by planting 15m strips of conventional cotton around each plot to act as a barrier and to monitor cotton pollen movement. Special emphasis was placed on the need to ensure GM cotton was not mixed with conventional cotton at harvest time. To ensure all seed could be accounted for farmers had to sow exactly three seeds per hill. With such a large programme it was anticipated that INERA scientists could not be at all locations for sowing, monitoring and harvesting, so extension technicians from the SOFITEX cotton company were additionally trained to oversee operations.

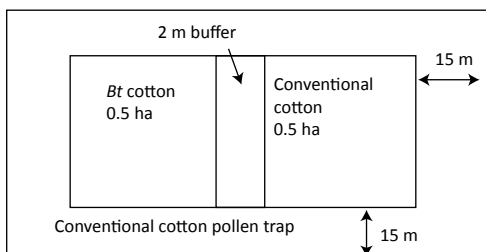
Extension technicians delivered the *Bt* cotton seed to each farmer in carefully sealed and labeled packets. Seed tracking was used to ensure any unused seed was returned to the research station. Extension workers oversaw initial planting and replanting when seed did not germinate. The *Bt* seed was lint-free and was planted 1cm deep; some farmers typically plant linted seed 2-3cm deep. In some cases improper seed depth led to low germination rates, requiring re-sowing. Harvesting was overseen by extension technicians and they transported all cotton to selected ginning facilities.

Stewardship

Durable packaging with thorough, clear labeling is important to ensure product integrity, a vital aspect of stewardship. The *Bt* cotton packets were clearly labeled 'Bollgard II™ seeds'. Each packet had the exact number of seeds so that extension technicians could track how



Farmers viewing the trials at an INERA training.



Planting diagram for the Bt cotton farmer trials



many seeds were used by each farmer and the number to be returned to the research station. Farmers were given packs of both *Bt* and conventional seed with *Bt* seeds dyed blue to differentiate between the seed types. Packets consisted of plastic bags lined with paper and an inner aluminium layer. The bags were kept securely closed until a cotton company agent opened them in a farmer's field.

Separation of GM and conventional seeds was maintained throughout the process – planting, harvesting and ginning – to ensure end product integrity. Before the trial and during the planting, all farmers received training on the importance of seed separation and how to do the separation. Due to the wide geographical distribution of the farmers, INERA staff could not personally oversee harvest, transportation and ginning. Critical control point (CCP) analysis was therefore used to identify and prioritise the aspects along the production chain requiring supervision by INERA and extension staff.

Because the farmer trials were done prior to the start-up of the SABIMA programme, scientists had not yet been trained in best stewardship practices and standard operating procedures (SOPs) had not been created for the farmer trials. But since 2010, with the guidance of the

Farmers and extension technicians learning about Bt cotton and stewardship practices from an INERA scientist.



SABIMA training, SOPs were written and used to create other CFTs, such as *Bt* cowpea which started in August 2011. Protocols on international practices were used as guidelines for SOP preparation. Tailoring protocols for each trial objective were essential in incorporating ideas by the lead INERA scientist, with input from extension technicians to enable clear steps for all farmers, scientists and extension technicians.

Challenges

INERA scientists faced a major challenge and dilemma when it became clear they were unable to personally oversee all plantings, monitoring, harvesting and ginning activities for the cotton grown by the 20 farmers. INERA decided the solution was to adapt its approach to more fully engage its partners and other stakeholders along the entire value chain, and to serve as a training and facilitating organisation.

Lessons

- Stewardship awareness and training is essential, not just for staff and stakeholders involved with early-stage research CFTs but also all along the development chain through to farmers commercialising *Bt* cotton.
- Larger-scale pre-commercial evaluation trials need special attention as the scale of testing and numbers of participating farmers increases, especially to prevent mixing of GM and conventional seed and entering the commercial cotton channel. Lead farmers are willing to comply with instructions when given, but it is important to have clear SOPs for them to follow.
- At this phase in product development and limited deployment, it is critical to have an integrated communication and awareness training programmes for all players in the product life cycle – researchers, developers, cotton company extension workers, seed producers, farmers, and staff at the ginning facilities.
- Creating CCPs and SOPs along the cotton production process from taking seed to farmers through to ginning will help to ensure product integrity and prevent inadvertent mixing of seeds. Tracking of product and verification procedures are essential to reduce the risk of cross-contamination. With the SABIMA stewardship training, INERA scientists are now able to do this and the learning is being applied to evaluation of the *Bt* cowpea and African bio-fortified sorghum research and development programmes in Burkina Faso.

*For more information on the experiences and stewardship principles covered in this case, please contact **Dr Hamiou Traoré** at hamitraore8@yahoo.com or **Dr Omer Héma** at omerhema@yahoo.fr.*

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Acronyms and abbreviations

AATF	African Agricultural Technology Foundation (Kenya)
<i>Bt</i>	<i>Bacillus thuringiensis</i>
CCP	critical control point
CFT	confined field trial
CSIR–CRI	Council for Scientific and Industrial Research–Crop Research Institute (Ghana)
CSIRO	Commonwealth Scientific and Industrial Research Organization (Australia)
DARS	Department of Agricultural Research Services (Malawi)
DDPSC	Donald Danforth Plant Science Center
DNA	deoxyribonucleic acid
FAO	Food and Agriculture Organization of the United Nations
FARA	Forum for Agricultural Research in Africa
GMO	genetically modified organism
HACCP	hazard analysis critical control point
IAR	Institute for Agricultural Research (Nigeria)
IBC	Institutional Biosafety Committee
INERA	Institut de l'Environnement et de Recherches Agricoles (Burkina Faso)
ISTA	International Seed Trade Association
KARI	Kenya Agricultural Research Institute
KEPHIS	Kenya Plant Health Inspection Service
MOFA	Ministry of Food and Agriculture (Ghana)
NaCRRI	National Crops Resource Research Institute (Uganda)
NARL	National Agricultural Research Laboratories (Uganda)
NARO	National Agricultural Research Organisation (Uganda)
NBC	National Biosafety Committee
NGO	non-governmental organisation
PCR	polymerase chain reaction
QUT	Queensland University of Technology (Australia)
SABIMA	Strengthening Capacity for Safe Biotechnology Management in Sub-Saharan Africa
SFSA	Syngenta Foundation for Sustainable Agriculture
SIT	sterile insect technique
SOP	standard operating procedure
USAID	United States Agency for International Development
VIRCA	Virus Resistant Cassava project
SSU	Seed Services Unit (Malawi)

About FARA

FARA is the **Forum for Agricultural Research in Africa**, an apex organisation that brings together and forms coalitions of major stakeholders in agricultural research and development in Africa. Its mission is to create broad-based improvements in agricultural productivity, competitiveness and markets by supporting Africa's sub-regional organisations (SROs) in strengthening capacity for agricultural innovation. FARA's value proposition is to provide a strategic platform to foster continental and global networking that reinforces the capacities of Africa's national agricultural research systems and SROs.

About SFSA

The **Syngenta Foundation for Sustainable Agriculture** (SFSA) is a non-profit organisation based in Basel, Switzerland. Our mission is to create value for resource-poor small farmers in developing countries through innovation in sustainable agriculture and the activation of value chains. With more than 20 projects in Asia, Africa and Latin America, SFSA's two-pronged approach aims to improve livelihoods by raising agricultural productivity and linking farmers to markets. For more information, please visit www.syngentafoundation.org.

About SABIMA

Strengthening Capacity for Safe Biotechnology Management in Sub-Saharan Africa (SABIMA) is a 3-year project (2009–2011) funded by SFSA and coordinated by FARA. It covers six sub-Saharan African countries: Burkina Faso, Ghana, Kenya, Malawi, Nigeria and Uganda. Its purpose is to strengthen Africa's capacity in sound biotechnology management for enhanced food security. Focal point scientists, the top researchers in biotechnology in their respective countries, undertake intensive SABIMA stewardship training, enabling them to conduct trainings for scientists in their countries.

The broad objectives of the SABIMA project are:

- Information gathering and dissemination
- Stewardship training and implementation
- Advocacy and awareness creation on issues of biotechnology and its stewardship

The project is managed by FARA and executed at country level by the national agricultural research systems (NARS) with regional oversight by the respective SROs. Detailed information on the SABIMA project is available on the FARA website www.fara-africa.org.



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