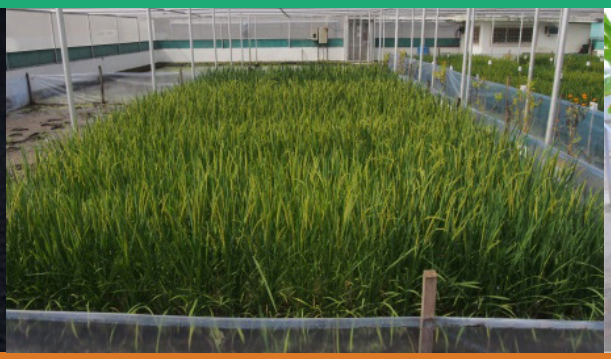
UGANDA NATIONAL COUNCIL
FOR SCIENCE & TECHNOLOGY

THE REPUBLIC OF UGANDA

PROCEEDINGS OF THE 2nd ANNUAL NATIONAL BIOSAFETY FORUM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UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Organized by: Uganda National Council for Science and Technology (UNCST) in partnership with Program for Biosafety Systems, OFAB Uganda Chapter

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ACKNOWLEDGMENTS

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Representatives of central government and parliament that graced the meeting namely: Hon. Elioda Tumwesigye – MP, Minister of Science, Technology and Innovation (MOSTI); Hon. Kafeero Sekitoleko [Chairman of the Science and Technology (S&T) Parliamentary Committee of Parliament]; Hon. Rose Mutonyi Masaba, Hon. Michael Timuzigu, Hon. Fred Bwino Kyakulaga (Members S&T Parliamentary Committee); and Mr. David O.O. Obong, (Permanent Secretary, MOSTI), are commended for the immense support provided to the STI sector and specifically policy support for integrating biotechnology in the development processes.

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Paper presenters and panelists, namely: Dr. Woldyesus Sinebo (ABNE), Dr. David Hafashimana (NARO), Mr. Herbert Oloka (PBS), Dr. Barbara Zawedde Mugwanya (UBIC-NARO), Dr. Jimmy Lamo (NARO), Dr. Jonathan Kayondo (UVRI), Dr. Andrew Kiggundu (NARL-NARO), Dr. Stephen Buah (NARL-NARO), Dr. Titus Alicai (NARO), Dr. Jerome Kubiriba (NARO), Mr. Abel Arinaitwe (NARO), Ms. Harriet Ityang (Ministry of Justice and Constitutional Affairs), Ms. Prospero G. Lonyo (UBBC), Dr. Geoffrey Arinaitwe, (Institutional Biosafety Committee, NARO), Mr. Francis Ogwal, (National Environment Management Authority), Ms. Irene Wanyenya (National Drug Authority), Mr. Issa Katwesigye (Ministry of Agriculture, Animal Industry and Fisheries), Ms. Jacqueline Kwesiga (Uganda National Bureau of Standards) and Dr. Theresa Sengooba (UNCST), thank you all for the insights and informative presentations.

Cover photos:

1. Transgenic CBSD-resistant TME204 cassava, source: T. Alicai, 2017
2. T1 IR64 Transgenic rice under CFT, source: O. Ricardo and J. Lamo, 2017
3. Tissue culture banana plantlets, source: S. Buah, 2017

LIST OF ACRONYMS

AATF	African Agricultural Technology Foundation
ABNE	African Biosafety Network of Experts
ABSP-II	Agricultural Biotechnology Support Project II
ACMV	African Cassava Mosaic Virus
Bt	Bacillus thuringiensis
BXW	Banana Xanthomonas Wilt
CBSD	Cassava Brown Streak Disease
CFT	Confined Field Trial
CMD	Cassava Mosaic Disease
CMGs	Cassava Mosaic Gemini viruses
DNA	Deoxyribonucleic Acid
dsRNA	Double Stranded Ribonucleic Acid
EACMV	East African Cassava Mosaic Virus
GM	Genetically modified
GMO	Genetically Modified Organism
HT	Herbicide Tolerance
IBC	Institutional Biosafety Committee
IITA	International Institute for Tropical Agriculture
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
MOSTI	Ministry of Science, Technology and Innovation
MWE	Ministry of Water and Environment
NaCRRI	National Crops Resources Research Institute - Namulonge
NARL	National Agricultural Research Laboratories - Kawanda
NARO	National Agricultural Research Organization
NaSARRI	National Semi-Arid Agricultural Resources Research Institute – Serere
NBC	National Biosafety Committee
NDA	National Drug Authority
PBS	Program for Biosafety Systems
PVA	Pro-Vitamin A
RNA	Ribonucleic Acid
RNAi	Ribonucleic Acid Interference
SCIFODE	Science Foundation for Livelihoods and Development
siRNA	Small Interfering Ribonucleic Acid
UBIC	Uganda Biosciences Information Centre
UNCST	Uganda National Council for Science and Technology
UVRI	Uganda Virus Research Institute
VAD	Vitamin A Deficiency

INTRODUCTION

1.1 Background

Uganda is recognized as the most prolific country in research and development in the area of genetic modification, in sub-Saharan Africa (Chambers,2013) Scientific experiments are conducted within the limits of existing policy, legal and institutional framework for research and technology development in general, that is the UNCST Act (1990, Cap 209), which permits experimental development at all stages, and other relevant laws such as the National Agricultural Research (NARO) Act, National Environment Management Act, among others.

It is in this context that UNCST, which is also the Competent Authority for Biosafety in Uganda organizes the National Biosafety Forum every February since 2016, provided a platform for interaction among various actors involved in biotechnology research and biosafety. The forum brings together researchers, regulators, policy makers, members of Institutional Biosafety Committees, and the Media to share experiences and discuss their scientific progress and the results of the experiments.

This year's Forum (2017) addressed: global biosafety trends and Uganda's readiness for environmental release of genetically modified (GM) crops; emerging gene techniques and implications for biosafety regulation; highlights of GM crop research in Uganda; and an update on Uganda's efforts towards having a fully-fledged biosafety regulatory system. The Forum was organized under the theme: **''Building Trust in Biosafety Regulation''**

1.2 Objectives

The objectives of the Forum were to:

- To facilitate continued interaction between the NBC, IBC, national regulatory agencies, key decision makers in government, and biotechnology scientists/researchers biotechnology in Uganda.
- Enhance stakeholders' understanding of Biosafety Research

1.3 Expected outcomes of the Forum

- Enhanced awareness by UNCST, NBC and other regulatory agencies, on current and anticipated scientific developments in GM technology.
- Increased regulatory agencies' capacities to make sound regulatory decisions.
- Improved implementation and compliance with national biosafety guidelines and regulations by researchers.
- Enhanced collaboration and partnerships for effective implementation of Biosafety regulations.
- A better understanding of the role of Biosafety in National Development by stakeholders.
- Proceedings with extended abstracts of the Forum presentations will be published.

Participants pose for a group photograph with the Minister and Permanent Secretary for the Ministry of Science, Technology and Innovation (MOSTI).

1.4 Participation

The one and a half-day meeting brought together over 112 participants drawn from academia, public and private research institutions, private sector, regulatory agencies, parliament and the media. The meeting was presided over by Hon. Elioda Tumwesigye – MP, the Minister of Science, Technology and Innovation (MOSTI). Notable among the participants were: Hon. Kafeero Sekitooleko [Chairman of the Science and Technology (S&T) Committee of Parliament], Hon. Rose Masaba and Hon. Michael Timuzigu, Hon. Fred Bwino Kyakulaga (Members S&T Parliamentary Committee), Mr. David O.O. Obong, (Permanent Secretary, MOSTI), Dr. Charles Mugoya (Chairman, National Biosafety Committee- NBC); Prof. John Opuda Asibo (Director National Council for Higher Education and former Chairman of the NBC) as well as Prof. Paulo Paes De Andrade who delivered the keynote speech. Prof. Paulo Paes de Andrade is a Professor of Genetics at the Federal University of Pernambuco, Recife, Brazil has for the last fifteen years been working on genetics and molecular biology of parasites and plants, as well as on genomics, transcriptomics and biosafety. He is the representative of the Ministry of External Relations at the National Authority for Biosafety (CTNBio) in Brazil.

SESSION ONE: OFFICIAL OPENING

2.1 Welcome remarks by Executive Secretary UNCST, presented by Dr. Maxwell Otim Onapa, Deputy Executive Secretary, UNCST.

Dr. Otim welcomed participants to the meeting. He acknowledged the presence of UNCST's partners, namely: Program for Biosafety Systems (PBS), Uganda Bioscience Information Centre (UBIC) at the National Agricultural Research Organization and Uganda Biotechnology and Biosafety Consortium (UBBC). He informed participants that the Biosafety Forum was conceived out of the need for a platform for scientists working with to GM technology interact with their peers and biosafety regulators. It is one of the mechanisms through which UNCST promotes public accountability and transparency in respect to Ugandan scientists' activities and the Biosafety system, respectively.

Noted that Uganda is one of countries in Africa that is currently actively undertaking field testing of GM crops. These are carried out within the limits of existing policy, legal and institutional framework for research and technology development, mainly the UNCST and NARO Acts, as well as the National Biotechnology and Biosafety Policy (2008) and other relevant policies of government. The Forum is held annually to ensure that stakeholders are abreast with contemporary issues pertaining to Biosafety.

In conclusion, Dr. Otim informed participants that the meeting would dedicate time to discuss the draft National Biotechnology and Biosafety Bill which was pending approval from Parliament of Uganda, he expressed optimism that in addition to providing an opportunity to network, the Forum would also identify priorities for biosafety research, policy and regulatory development in Uganda.

2.2 Remarks by Dr. Charles Mugoya, Chairman, National Biosafety Committee (NBC)

Dr. Mugoya informed the meeting that the NBC, one of UNCST's standing committees had been in place for almost 20 years, and that the 75 or more Ugandans of diverse professional backgrounds, who have served on the NBC since its inception, constitute the Biosafety human resource the country boasts of.

The NBC is a multi-sectoral and multi-disciplinary committee and therefore can handle diverse aspects of biosafety. Their oversight role has seen them successfully preside over Sixteen (16) Controlled Field Trials (CFTs) in Uganda, from experimentation to final end result.

The NBC Chairman however regretted that the Committee was not yet able to oversee any environmental or commercial release of GM crops in Uganda because lack of an enabling law. He observed that having the law for Biotechnology and Biosafety would empower the NBC to fully perform their functions. He thanked Prof. John Opuda -Asibo (former chairman, NBC) and members of the NBC for their dedicated service; and UNCST for hosting the 2nd National Biosafety Forum and supporting NBC.

2.3 Remarks by Dr. Theresa Sengoba, Chairperson, UNCST.

Dr. Theresa Sengooba (Chairperson, UNCST) commended His Excellency the President and Government of Uganda for their commitment to fostering science and technology-led development, as evidenced in the creation of a substantive Ministry for Science, Technology and innovation (MOSTI) and appointing a committed and competent scientist to lead the Ministry. She thanked the Minister for STI for the immense support for UNCST's initiatives; and recognized the NBC for exhibiting competence in handling biosafety matters in Uganda.

Dr. Sengooba commended scientists for actively engaging in scientific activity that is advancing Uganda's biotechnology development. She noted that there were 7 applications for Controlled Field Trials (CFTs) in the pipeline, which were focusing on: banana, maize, cassava, rice and potatoes, among others. She however reiterated that environmental releases of these genetically modified crops could not proceed due to lack of appropriate legislation. She assured Ugandans that the country has capacity for conduct environmental release of GM crops.

2.4 Remarks by Mr. David. O.O. Obong, Permanent Secretary, Ministry of Science Technology and Innovation (MOSTI).

The Permanent Secretary thanked the scientific community for their efforts to advance STI development in Uganda. He further commended the Minister for STI for progress made in establishing this maiden Ministry.

Mr. Obong underscored the need for a comprehensive communication strategy for biosafety, that is translated into local languages, as a means of effectively engaging the public on issues of biotechnology and biosafety.

In conclusion he pledged to provide the technical leadership that would spur the science and technology sector to the heights envisioned in the National development framework.

2.5 Remarks by Hon. Dr. Elioda Tumwesigye – MP, Minister of Science Technology and Innovation.

In his remarks, Hon. Tumwesigye was happy to observe that Ugandan scientists had already found solutions to the challenges of poverty, disease burden, food insecurity and the long spells of drought, which Uganda is grappling with. He thanked government for the enabling political environment that is very supportive of science, technology and innovation (STI).

He regretted that owing to the absence of a law for the safe application of biotechnology in Uganda, their innovations which include: maize, bananas, potatoes, cassava, and rice, that are resistant to different diseases, pests or drought tolerant, among others, with potential to help modernize agriculture and improve livelihoods, cannot yet be deployed on farms. He however commended scientists for preparing in advance and was happy to note that through these efforts the country has high prospects for a booming bio-economy.

In conclusion he assured Ugandans that his Excellency the President and the Government of Uganda are convinced of the outstanding benefits of biotechnology and that the National Biotechnology and Biosafety law will be passed after conclusion of ongoing public consultations. He pledged that his Ministry will continue to take the lead in this endeavor. The Minister applauded Prof. de Andrade for sharing Brazil's experience through his informative and educative keynote speech.

SESSION 2: GLOBAL BIOSAFETY TRENDS AND UGANDA'S READINESS TO GM ENVIRONMENTAL RELEASE OF GM CROPS

Chairman: Prof. Opuda-Asibo, Executive Director, National Council for Higher Education

3.1 Keynote - Emerging global trends and best practices in biosafety regulation in Latin America: what lessons are we learning? By Prof. Paulo Paes de Andrade, Department of Genetics, Federal University, Pernambuco, Recife, Brazil.

The Brazilian Scenario for biosafety regulation before prior to passing of their bill into law in 2004 was characterized by numerous institutions with mixed up responsibilities. There was use of poorly defined laws and decrees and a lack of experience in regulation. This led to a de facto moratorium from 1998 on smuggling of Genetically Modified (GM) soybean seeds from Argentina and large-scale planting in the southern provinces of Brazil in 2003. This legal uncertainty discouraged trade and research by both academics and private sector, which in turn led to a buildup of pressure from these stakeholders for a new biotechnology law. The law on biotechnology was passed in 2004 and the Brazilian GM regulatory and management scenario changed for the better.

The process for the evaluation of a GM product (any GMO) intended for commercial (general) release in Brazil runs for a period between 4.5 and 10 years. The process begins with submission of a request to the Executive Secretary of CTNBio (Brazil's Biosafety regulatory agency) for initial review by staff. After a processing of application, it goes through public consultation for a period of 30 days. The processed application is then distributed among a few members of the four chambers for technical opinions and discussion of the technical opinions within each chamber then follows. The technical opinions are subjected to a vote in the plenary session. The decision is then published and sent to the enforcement and registration agencies. The CNBS (equivalent of NBC) takes 3 months to 10 years to analyze the decision. To date, there has not been a single case of rejection of a CTNBio decision. CTNBio has partially played the role as risk manager and left it to the market to decide which GM products they deem useful. The comprehensive legal framework for biosafety has led to commercial (general) release authorizations and GM crop adaption in Brazil. 94.2% of Soy bean, 84.6% of Maize and 73.3% of Cotton in Brazil are GM crops. The legal framework has also allowed for commercial release of many other GMOs (besides plants) like vaccines from transgenic viruses, drugs and biological molecules from transgenic microorganisms (bacteria & yeasts), oils and second generation ethanol from micro-algae and yeasts and Insects for biological pest control.

3.2 Regional commitments and actions in biosafety regulation: is Africa moving forward? By Dr. Woldeyesus Sinebo, NEPAD agency ABNE.

A report of High-Level African Panel on Modern Biotechnology stated that "regional economic integration in Africa should embody the building and accumulation of capacities to harness and govern modern biotechnology."

Some African states have made some progress towards building the biosafety frameworks as summarized below:

Biotechnology and Biosafety Milestone	Number and names of Countries that have achieved the Milestone
GM commercialized crops	3 - Burkina Faso, Sudan, South Africa
CFTs ad biosafety laws	11 - Burkina Faso, Cameroon, Egypt, Ethiopia, Ghana, Kenya, South Africa, Nigeria, Malawi, Sudan, Swaziland
CFT without laws	1 - Uganda;
Biosafety laws without CFTs	10 – Namibia, Zambia, Zimbabwe, Mozambique, Tanzania, Togo, Mali, Senegal, Tunisia
Recent environmental release approvals	3 - Nigeria, Malawi, Kenya
No biosafety laws or CFTs, no GM commercialized crops	31- the rest of African Countries

The overall emerging trend in Africa is an increased understanding of biotechnology and biosafety issues. More countries are progressively coming up with informed positions and safe deployment of biotechnology for agricultural development.
The table below highlights recent African countries' actions in the areas of biotechnology and biosafety.

NIGERIA The Biosafety Law was assented. The environmental release of Bt cotton and field testing of WEMA maize has been approved.
BURKINA FASO There were some glitches with commercialized Bt cotton varieties because of discord between the cotton companies and Monsanto on fiber length resulting from inadequacy of back-crossing with the conventional cotton varieties. This issue is not related to the Bt technology but to compliance with the standard conventional back-cross breeding procedure.
Malawi The environmental release of Bt cotton has been approved. There are controlled field trials for Bt cowpea and GM banana that have commenced.
ETHIOPIA There have been revisions made to the Biosafety Proclamation and Biosafety Directives. This has resulted in improved environment for functionality of the biosafety process. There is close coordination among the Ministry of Environment and Forestry, the Ministry of Agriculture and Ministry of Science and Technology, on matters concerning biotechnology and biosafety. Multi-location Trials of Bt cotton are ongoing at seven locations
KENYA Environmental releases of WEMA maize varieties and Bt Cotton have been approved for conducting National Performance Trials.
TANZANIA The Biosafety Act has been revised to make research and product development more workable. Controlled Field Trials of the WEMA maize varieties are in progress.
MOZAMBIQUE The Biosafety Decree has been published and Controlled field trials are expected to commence soon.

3.3 Highlights of decisions taken in COP-MOP of the Cartagena Protocol on Biosafety, by Dr. David L. N. Hafashimana, National Agricultural Research Organization.

The Cartagena Protocol on Biosafety that came into force in September 2003, now has 70 parties worldwide, including Uganda. The 8th meeting of the COP/MOP took place in Cancun, Mexico, in December 2016.

A total of 19 decisions were adopted, some of which have a bearing or impose obligations on the parties to the protocol, with others conferring benefits to some or all parties. The following are some of decisions which require Uganda's action:

1. Urged Parties that have not yet completely put in place legal, administrative and other measures to implement their obligations under the Protocol, paying particular attention to the importance of putting in place monitoring systems as a prerequisite for effective reporting;
2. Encouraged Parties and other Governments to consider nominating experts for the roster on biosafety experts in areas where there is a lack of expertise on the current roster, for example, in the areas of management of data related to biosafety and biodiversity, socio-economic analysis and trade, synthetic biology, and public awareness, education and participation;
3. Encouraged parties to continue to make specific funding available to eligible Parties to put in place their national biosafety frameworks. To continue to fund projects and capacity-building activities on issues identified by the Parties to facilitate further implementation of the Cartagena Protocol on Biosafety, including regional cooperation projects with a view to facilitate the sharing of experiences and lessons learned, and harnessing associated synergies;
4. Urged Parties to improve and strengthen collaboration at the regional and national levels among focal points of organizations, conventions and initiatives relevant to the implementation of the Biosafety Protocol, as appropriate;
5. Encouraged Parties to make use of the Biosafety Clearing House (BCH) to share experiences on national processes and best practices related to socioeconomic considerations in decision-making related to Living Modified Organisms (LMOs), as appropriate, and in accordance with national legislation;
6. Noted that a lack of awareness and political support for biosafety issues contributes to limited access to and uptake of funding for biosafety, and urges Parties to enhance efforts to raise awareness of key biosafety-related issues among policy- and decision-makers;
7. Invited Parties to provide information regarding their capacity and needs in the detection and identification of LMOs, including a list of laboratories and their specific activities; Encouraged Parties to establish effective mechanisms to support the workflow for sampling, detection and identification by, for example, providing border control officials and laboratories with the appropriate mandates to sample, detect and identify LMOs;
8. Encouraged Parties and invites other Governments to make available to the BCH their laws, regulations and guidelines regarding contained use and transit of LMOs;

3.4 Uganda's readiness for environmental release of GM crops, by Dr. Barbara Zawedde, Uganda Biosciences Information Center (UBIC), NARO.

An interim system for biosafety was established within the provisions of the UNCST Statute, in mid 1990s, to address applications from scientists in Uganda to test GMOs which at the time included the Bovine Somatotropin hormone and a Candidate HIV-1 vaccine.

The system has since evolved as GM crop research in Uganda progresses. There is GM crop research at contained research stage, that is, in laboratories and green or screen houses, for example nematode- resistant banana, and fungal-resistant groundnuts. Others GM crops under confined field testing stage include the following Transgenic banana resistant to banana bacterial Wilt, Transgenic Banana resistant to Black sigatoka disease, Tansgenic banana bio-fortified with Vitamin A and Iron, Transgenic cotton resiatant to Cotton Boll worm, Transgenic cotton tolerant to herbicide, Transgenic Maize tolerant to drought stress, Transgenic maize resistant to Stem borer , Transgenic potato resistant to Phytophthora infestans that causes Potato Late Blight Disease etc

In order to effectively prepare for general release of GM crops, there is need to build more capacity in, data interpretation and transportability, environmental risk assessment (RA) and risk management (RM), post-release monitoring in the different government agencies charged with biosafety work such as the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF), National Environmental Management Authority (NEMA), Uganda National Bureau of Standards (UNBS), and UNCST. Uganda's readiness for environmental release will further be strengthened by developing an inventory of protected ecological entities, continued risk assessment capacity building in the NBC , institutional biosafety committees (IBCs), as well as independent risk assessors and regulatory managers.

3.5 Status of capacity development for biosafety regulation by Mr. Herbert Oloka, Program for Biosafety Systems.

The Program for Biosafety Systems (PBS) provides direct technical and logistical support in development the biosafety regulatory framework in Uganda. The main country partner is UNCST.

In the 2000s, capacity development efforts were initiated by several development partners such as: Sida-SAREC, United Nations Environment Program/GEF (UNEP), USAID, through programs such as: Program for Biosafety Systems - PBS, the East African Regional Program and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIOEARN, now BioInnovate), among others. These efforts focused on: graduate training at MSc and PhD level; compliance management, building institutional systems, inspections, risk assessment and management: preparation of Dossiers; and biosafety reviews.

The capacity to conduct GM research is sufficient but the challenge is the limits on general release of GM crops. Biosafety facilities exist and there is sufficient human resource to work in these facilities. Expertise will be needed for risk assessment for general release and risk communication. The absence of explicit legislation for biotechnology and biosafety in Uganda has denied Ugandans the opportunity to optimize these human and infrastructural resources. It is envisaged that the Biosafety Law will provide the mandate for relevant institutions to build the requisite biosafety capacities.

SESSION 3: EMERGING GENE TECHNIQUES AND IMPLICATIONS FOR BIOSAFETY REGULATION

Chairman: Dr. Charles Mugoya, Chairman National Biosafety Committee

4.1 Recent advances and controversies with gene editing techniques (and synthetic biology), by Dr. Paulo Paes de Adrade, Federal University, Pernambuco Recife, Brazil.

Gene editing is a novel way of deleting or inserting one or more base pairs in a genome. The target position is precisely determined. Some results of gene editing include: gene activation, gene repression, gene knock-out, imaging genomic loci, genome-wide screening and purification of genomic loci.

The Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) Type II system is a bacterial immune system that has been modified for genome engineering. CRISPR consists of two components: a "guide" RNA (gRNA) and a nonspecific CRISPR associated endonuclease (Cas9). The gRNA is a short synthetic RNA composed of a "scaffold" sequence necessary for Cas9 binding and a user-defined 20 nucleotide "spacer" or "targeting" sequence which defines the genomic target to be modified. One can change the genomic target of Cas9 by simply changing the targeting sequence present in the gRNA. CRISPR was originally employed to "knockout" target genes in various cell types and organisms. Modifications to the Cas9 enzyme have extended the application of CRISPR to selectively activate or repress target genes, purify specific regions of DNA, and even image DNA in live cells using fluorescence microscopy. Furthermore, the ease of generating gRNAs makes CRISPR one of the most scalable genome editing technologies

If the CRISPR/Cas9 and the guide RNA (more precisely, a DNA encoding it) are cloned in a chromosome, the system will edit the other chromosome in the same precise location and the cell will become homozygous for this genetic mark. All cells derived from these cells will be also homozygous Haploid, reproductive cells will generate homozygous somatic cells, even if only one haploid cell carries the editing system. The effect is called 'gene drive'.
A gene drive can change a whole population. Fast growing populations (e.g., insects, some small mammals, algae, some clams, etc.) are suitable to population modification or suppression by the introduction of individuals having a gene drive. A small number of gene drive mosquitoes could potentially change a whole population of mosquitoes from the same species or lead to its local eradication. Possible applications of gene drive include; Pest control, Generation of transgenic (homozygous) animals or plants and Gene therapy
Synthetic biology has no single consensual definition, but it is agreed that, the new organism must have precisely engineered parts (coded in its DNA or RNA) to perform specific functions. These parts must be designed de novo (and not directly cloned from other organisms). Usually a couple of simultaneous modifications are introduced.

The controversies with synthetic biology are many and include;
It creates "entirely new organisms" and therefore no possible comparator for risk assessment;
The results of synthetic biology are "too complex new organisms" which makes risk assessment too difficult;
It results in "brand new, unnatural proteins/enzymes, with unexpected results" and therefore there is no way to assess risks.

4.2 Development of bacterial leaf blight disease resistance in rice through CRISP cas9 gene editing techniques, by Dr. Jimmy Lamo.

The Bacterial leaf blight disease is considered the major rice bacterial disease due to its high epidemic potential, especially under extreme climatic variations, and its destruction of high-yielding rice cultivars. Despite attempts to control the disease by incorporating genetic resistance into high-yielding cultivars, the disease remains a major constraint to Asia and Africa. Yield losses ranging from 20% to 100%, have been reported. Efforts are ongoing to develop bacterial leaf blight disease resistance in rice through CRISP Cas9 gene editing techniques.

CRISPR is actually a naturally-occurring, ancient defense mechanism found in a wide range of bacteria. Its DNA sequence is repeated over and over again, with unique sequences in between the repeats. The unique sequences in between the repeats matched the DNA of viruses—specifically viruses that prey on bacteria.
The second part of the defense mechanism is a set of enzymes called Cas (CRISPR-associated proteins), precisely snip DNA. Conveniently, the genes that encode for Cas are always near the CRISPR sequences. As the CRISPR region fills with virus DNA, it becomes a molecular defense set, representing the enemies the microbe has encountered. The microbe can then use this viral DNA to turn Cas enzymes into precision-guided weapons. The microbe copies the genetic material in each spacer into an RNA molecule. Cas enzymes then take up one of the RNA molecules and cradle it. The viral RNA and the Cas enzymes drift through the cell, if they encounter genetic material from a virus that matches the CRISPR RNA, the RNA attaches on.
The Cas enzymes then chop the DNA in two, preventing the virus from replicating. CRISPR/Cas9 uses small “guide RNA” molecules together with a scissor-like enzyme to find and snip the specific. Cas9 hones in on the targeted viral DNA and cuts it away. The Cas9 can be fed the right sequence, called a guide RNA then be able to you can cut and paste bits of DNA sequence into the genome wherever you want. Cas9 can recognize a sequence about 20 bases long. DNA is repaired by the cell and the deleted piece of DNA is replaced with a substitute portion of DNA.
(See Annex 3, Abstract 1 by Lamo and Ricardo for details).

4.3 Gene Drive for Malaria Control, by Dr. Jonathan Kayondo, Uganda Virus Research Institute (UVRI).

There are more than 200 million malaria infections and half a million deaths each year due to malaria. Approximately 90% of the infections and deaths are in Africa. Economic losses due to malaria are approximately US$12 billion a year in Africa.

Malaria is caused by a parasite called Plasmodium which is spread to humans through the bites of infected mosquitoes. In Africa most transmission is by 3 closely related species (Anopheles gambiae, A. coluzzii and A. arabiensis), plus A. funestus. Only female mosquitoes bite and transmit the parasite.

There are many new innovations in progress to curb malaria which include;

- Drugs: single dose radical cure will be extremely useful, but will not be able by itself to eliminate malaria from high intensity regions
- Vaccines: the global health community has called for development and licensing of vaccines with 75% efficacy by 2030. Allowing for 80% coverage, implies 60% transmission reduction which useful, but not sufficient for eradication of malaria
- Insecticides: next generation chemicals or biological mostly aiming to maintain current pyrethroid levels of control in the face of resistance, rather than improvement

Genetic approaches for malaria control entail taking into consideration what changes to effect in the mosquitoes and how to spread those changes throughout the population in a meaningful timeframe. Most genetic modifications would remain at a very low frequency in the population or be lost due to selection or drift.
Gene drive-based modification entails genetic modification of the target insects to affect fertility or other traits, such as the ability to carry a parasite. It is meant to be self-sustaining, that is, the selected gene is passed on from generation to generation, spreading through the target population. Gene drive-based modifications are best suited to controlling diseases such as malaria which are spread over large and remote areas. Gene drive increases the odds of a gene by causing biased inheritance of itself among offspring.
Issues that may be of concern in the use of gene drive based modifications include: resistance, effects on biodiversity and the ecosystem; governance and public acceptance. Currently there is no modified mosquito research going on yet, the laboratory studies that are ongoing are still in the early stages.

4.4 Synthetic biology: what is in it for Uganda and Africa? By Dr. Andrew Kiggundu, National Agricultural Research Organization.

Synthetic biology is a new area of biological research that combines biology and engineering. It encompasses a variety of different approaches, methodologies and disciplines, and many different definitions exist. It entails the design and construction of new biological functions and systems not found in nature, which may range from biomolecules to organisms.

The Genetic Code is Universal and therefore, genes from one species can be transferred into another species. The fundamental physical and functional unit of heredity, which carries information from one generation to the next, a segment of DNA, composed of a transcribed region and a regulatory sequence that makes transcription possible.
Potential applications of synthetic biology range very widely across scientific and engineering disciplines, medicine, environment and energy generation. Synthetically designed microorganisms can improve production of pharmaceutical compounds that are extremely challenging for existing methods of chemical or biological synthesis. New drug development pathways such as the construction of an artificial metabolic pathway in E. coli or yeast to produce the antimalarial drug artemisinin. Another potential use of synthetic biology is in the area of bioremediation and biosensors. Microorganisms and plants can be engineered to degrade pesticides and remove pollutants from the environment while biosensors can be developed to detect toxic chemicals. Synthetic biology may be used to produce biofuels by engineering microorganisms to produce carbon-neutral (or more environmentally friendly) sources of energy.

The growth of the Internet makes sequence information and biotechnological procedures, the tools for doing synthetic biology easily accessible. Machines can be instructed to create codes as the beginning of synthesis of biological systems. The major biosafety risk of synthetic biology is the accidental release of synthetic organisms, which are self-propagating and could have unintended detrimental effects on the environment or on human health. It is important to note that before thinking of regulating synthetic biology it must be well defined.

SESSION 4: STATUS OF GM CROP RESEARCH IN UGANDA

Chairman: Prof. John Enyaru

5.1 Developing cooking bananas with enhanced pro-vitamin A content, by Dr. Stephen Buah, NARO- National Banana Research Program.

Vitamin A deficiency is the Leading cause of blindness among children. More than 35% of women and children in Uganda suffer from vitamin A deficiency. Vitamin A deficiency increases the risk of death from common infections among young children.

Most popular banana cultivars grown in Uganda are essentially sterile while the few that are fertile only rarely produce seeds. The sources of useful traits that are used for breeding purposes are often found in the wild varieties which are not edible. As such, these usually transfer characteristics that give hybrids poor taste. Backcrossing to increase levels of preferred traits is therefore not feasible. Genetic engineering is one reasonable means of developing improved bananas that maintain the desired taste.

The aim of developing cooking bananas with enhanced pro-vitamin A content is to alleviate micronutrient deficiencies, particularly vitamin A deficiency (VAD) and iron deficiency anemia (IDA), in Uganda through the micronutrient enhancement of bananas. Because banana is a major staple food in Uganda, vitamin A enhancement ensures that populations dependent on banana are able to access it in the diet. So far, the Ugandan scientists have generated and maintained embryogenic cell suspensions and achieved optimization and transformation of both M9 and Nakitembe cultivars. Regeneration, micropropagation, rooting, weaning and characterization of transgenic and control lines have successfully been done.

Confined Field Trials (CFT) of hardened lines have been running since August 2014 and the analysis of fruit provitamin A (PVA) levels using HPLC, have been conducted. The Selection of the best transgenic lines was based on two key priority criteria: BCE Levels (20 µg/g DW) and Yield (16 Kg for M9; 12 Kg for Nakitembe). About 59% of the selected M9 lines are of pGen2-M (ACO promoter) and over 62% the pGen2-P high PVA M9 lines were not selected due to yield penalty.

The team will continue a sustained fruit analysis up to ratoon 2 whenever possible and continue collecting and compiling phenotypic and agronomic data of all CFT plants up to second ratoon.
(See Annex 3, Abstract 3 by Buah et al. for details).

5.2 Developing resistance to banana bacterial wilt, by Dr. Jerome Kubiriba, NARO

Within a four years (between 2001 and 2005), Banana bacterial wilt (BBW) rapidly spread to 28 districts of Uganda by attacking all the banana varieties grown by farmers. BBW is predicted to destroy 90% of Uganda's bananas in 10 years if not controlled, and this translates to an equivalent of US$ 4 Billion loss of income and yet more than 20 million Ugandans depend on the bananas worth over US$ 534 million annually.
Cultural practices for control of BBW are labor-intensive and there is no source of resistance in existing banana parents and it is there impossible to employ conventional breeding methods. Two genes (HRAP and PFLP) were obtained from common sweet pepper (Capsicum annum). The 2 genes enhance the hypersensitive response (HR) action in cells. PFLP is a ferredoxin-like amphipathic protein and HRAP a hypersensitive response-assisting protein.

BBW resistance tests have gone past the proof of concept where 11 lines showed 100% resistance in field for 3 generations. BBW resistant lines were selected under screen house and advanced to multi-locational trials. Multi-locational evaluation of BBW resistance was approved and the NBC verified the proposed sites for BBW CFT at Mbarara Zonal Agricultural Research and Development Institute (ZARDI) and Bulindi ZARDI.

5.3 Multi-location evaluation of transgenic cassava cultivar TME 204 for Cassava Brown Streak Disease resistance, agronomic performance and adaptability, by Titus Alicai, National Crops Resources Research Institute – NARO.

Cassava, introduced to Uganda in the 1850s is now an important staple crop in Uganda. Cassava is a food and income security crop. More than 90% of cassava produced goes to the domestic market. Cassava Brown Streak Disease (CBSD) present in 51 out of 54 districts surveyed in 2014, up from 1 district as of 2004 surveys.

The RNAi-based technology is aimed at enhancing cassava's natural immune system capacity to fight off viruses that cause CBSD. CBSD is caused by two related but distinct virus species of family Potyviridae, namely: Cassava brown streak virus (CBSV) and Ugandan cassava brown streak virus (UCBSV). The coat protein genes of both viruses were designed as an inverted repeat fusion construct to target the two CBSD virus species. The TME204 was identified as the target cultivar because it is widely grown and favored by famers in Uganda, and has very good resistance to yet a different virus disease, cassava mosaic disease (CMD), imparted by CMD2 but is highly susceptible to CBSD. A total of 425 independent transgenic plant lines were produced between June 2011 and April 2012 with construct p5001. 350 plant lines were screened for low copy (1-2), no VBB integration and siRNA accumulation and 52 (c. 15%) met low copy, VBB free and siRNA accumulation requirements.

TME204 plants resistant to CBSD exhibited symptoms of cassava mosaic disease. This was associated with a certain variety of cassava cultivars with CMD2. After grafting five out of nine transgenic lines tested resistant to CBSV and UCBSV remained symptom-free and no virus detectable by RT-PCR all five resistant events were high accumulators of transgenic siRNAs, implying that the resistance might be transmissible mechanically by grafting.
16 TME204 lines free of CBSD foliar symptoms at 12 months after planting. Resistance correlated positively with levels of transgenic siRNA expression. Transgenic p000lants showed very high CBSD resistance at 12 months after planting.
The following observations were made;

1. Very high levels of CBSD resistance imparted by siRNA strategy – p5001 construct
2. Highly effective control of CBSD in the field
3. Resistance maintained over three growing cycles and in three geographic locations (Namulonge, Serere, Mombasa [Kenya])
4. No RT-PCR detectable virus in asymptomatic plants
5. Susceptibility to Cassava Mosaic Disease in p5001 TME204 lines and other TME types due to embryogenesis; cross pollination on-going to move the resistance into other farmer-preferred varieties
6. New product lines based on transformation of NASE 13 (NaCRRI) and NASE 14 (DDPSC) with same proven p5001 construct for quick deployment to the field.

(See Annex 3, Abstract 4: by Alicai et al. for details).

5.4 Off-patent GM technologies: a case for herbicide tolerant soybean in Uganda, by Prof. Phinehas Tukamuhabwa, Makerere University.

The technology deployed for transformation the soybean follows the expiry in 2015 (20 years later after protection) of a patent for the roundup ready soybean trait. The Roundup ready soybean (RRS) is tolerant to glyphosate, an active ingredient in Roundup, broad-spectrum

herbicide. The Benefits of RR soybeans are that it allows for the application of environmentally sound herbicide, wide-spectrum weed control option.
RR soybean was developed by recombinant DNA technology, through introduction of a glyphosate tolerant form of the enzyme 5- enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene. The gene was isolated from Agrobacterium tumefaciens strain CP4. Glyphosate tolerant gene in RR soybean codes for a bacterial version of EPSPS enzyme, highly insensitive to inhibition by glyphosate. RR soybeans are tolerant to glyphosate and are able to produce EPSPS enzyme that fulfills the aromatic amino acid metabolic needs of the plant.
The initial hybridization and early generation progeny testing will be carried out in a Screen house at Makerere University Agricultural Research Institute, Kabanyolo (MUARIK). The most elite single plants selected at back cross 3 (BC3). Determination of cost benefit analysis will be carried out in confined field trials at NACRRI, Namulonge. These experiments will also be carried out at 2 other locations where NACRRI has confined facilities.

5.5 GM potatoes expressing 3R genes showing high resistance to late blight disease in a confined CFT in Uganda. What does it mean for farmers, traders and consumers? By Mr. Abel Arinaitwe.

The average farm yield of potatoes has stagnated at 7.5 t/ha (UBOS, 2010). The high yield gap is mainly attributed to a number of production constraints including, pests and diseases (mainly Late blight and bacterial wilt), poor quality seed and climate - related issues among others. The Late Blight (LB) disease of potatoes can cause serious economic loss estimated at UGX505 billion annually. The most economically viable and environmentally means of controlling late blight is enhancing natural resistance of the potato through breeding.

New genes were discovered from potato relatives for resistance to late blight. Using biotech approaches they were introduced in to two potato varieties (Victoria and Desiree). Traditional breeding techniques have had limited success in breeding for LB resistance due to the absence of durable resistance genes in the crop's own germplasm. New R genes (RB, Rpi-blb2 and Rpi-vnt1.1) have been discovered and cloned from Solanum bulbocastanum and S. venturii for resistance to late blight.

Their introgression through conventional breeding of 2 or 3 R genes from different wild species would take several decades of crossing and selection due to the genetic drag from wild species, which is difficult to eliminate in an out-crossing tetraploid crop species. Genetic transformation provides a simpler solution to incorporate 2 or 3 genes without affecting the other traits. Three (3) resistance gene construct including RB/Rpi-blb1 and Rpi-blb2 from Solanum bulbocastanum (Mex) and Rpi-vnt1.1 from S. venturii (ARG). 3R gene stack made of [RB, Rpi-blb2 and Rpi-vnt1.1]

Screening for resistance to late blight was conducted to assess the effectiveness of the 3R gene stack to control late blight. During harvesting, it was observed that all transgenic events produced marketable tubers, unlike Desiree and Victoria the non-transgenic. The tuber shape, color of skin and flesh were however not different from the normal expected characteristics.

Key findings from CFT2, CFT 3 and CFT 4 were that these potatoes expressing resistance genes from their relatives hold the key for control of Late blight in Uganda. Future trials will measure yield of transgenic events as compared to the controls that are protected by fungicide applications.

SESSION 5: UGANDA'S EFFORTS TOWARDS A FULLY-FLEDGED BIOSAFETY REGULATORY SYSTEM

Chairman: Dr. Charles Mugoya

6.1 The National Biotechnology and Biosafety Bill, 2012: Highlights on the Progress trends, challenges towards the enactment into Law, by Ms. Harriet Ityang, Ministry of Justice and Constitutional Affairs.

Uganda ratified the Convention on Biological Diversity (CBD) in 1993 and the Cartagena protocol on biosafety in 2001. The Cartagena Protocol on biosafety is the legally binding international instrument with extensive provisions on the obligations of states on issues of Genetically Modified Organisms (GMOs). Uganda is therefore obligated to take necessary and appropriate legal, administrative and other measures to implement obligations under the protocol.

The main objectives of the National Biotechnology and Biosafety Bill are to provide a regulatory framework to ensure safety in the development and application of biotechnology and strengthen consumer protection and public awareness in the use of biotechnology. The Bill provides for every application for research or general release to include an emergency plan complete with safety measures for unintentional release of a GMO.
UNCST, the Competent Authority on Biotechnology and Biosafety issues in Uganda, according to the bill may stop unapproved GMO activities or an activity that threatens human health or environmental integrity. The competent authority is mandated to issue restoration orders in the event of damage to human health and the environment and investigate any claims concerning GMO activities.
If the Bill is passed, the institutions that are handling various elements of the Bill will be strengthened to implement these functions more effectively.
After consultation with the Competent Authority, regulations will be developed to better implement the provisions of the Act (when passed). The regulations will;

1. Prescribe procedures for research involving GMO;
2. Prescribe procedures for general release of GMOs into the environment;
3. Guide on handling, transport, identification, and packaging of GMOs;
4. Specify the fees for applications and other services under the Act;
5. Specify the safety levels and standards for safety of GMOs; and
6. Establish procedures for bio-ethical considerations in biotech research.

Currently, the Bill is with the Ministry of Science, Technology and Innovation, supported by the Ministry of Agriculture, Animal Industry and Fisheries. The Biotechnology and Biosafety bill is before the Parliamentary Committee on Science and Technology, after which, it will be presented for the second reading in Parliament.

The biggest challenge in trying to pass the Bill is the propaganda from anti-GMO activism, which have spread a lot of misinformation that has in turn prejudiced the technology. The public is not yet adequately sensitized, creating the mentality that biotechnology is harmful to humans, animals and the environment. Also, the previous positive sanitization to the previous parliament were largely annulled by the fact that the new parliament is composed of more than 60% new members of parliament, previously not sensitized about the bill and biotechnology in general. There is also fear that multinationals are promoting the technology, making it risky for smallholder farmers who might not be able to compete.

Parliament's consideration of the Bill was further by the expiry of tenure of the previous S&T Committee of Parliament whose decisions on the Bill could not be inherited by the new committee.

6.2 Biotechnology and Biosafety Policy outreach: Efforts, lessons, challenges by Mr. Erostus Nsubuga.

The main goal of the biotechnology and biosafety policy outreach is to build stakeholder understanding on relevant legislation. Stakeholders targeted include: policy makers, farmers, scientists, researchers, technocrats, private sector and the media.

A key challenge facing biotechnology and biosafety policy outreach in Uganda is the dynamism among policy makers especially in Parliament. This has resulted in the need to facilitate continuous sensitization of group of decision-makers

Despite the challenges, the opportunities for the biotechnology and biosafety policy outreach are quite many. The increased interest and support from high level policymakers, presidential pronouncements, ministerial statements, increased farmer voices demanding for solutions and passage of the bill and the creation of Ministry of Science, Technology and Innovation are all a step in the right direction. These provide the much needed boost for the biotechnology and biosafety policy outreach programs to achieve their goals.

6.3 Round Table Discussions on a Coordinated Framework for GM Crop Regulation: Focus on Institutional Roles in Biosafety Regulation.

Moderators: Dr. Charles Mugoya and Dr. Sarah Ssali

Panelists: Dr. Geoffrey Arinaitwe, Institutional Biosafety Committee, NARO
Mr. Francis Ogwal, National Environment Management Authority/MWE
Ms. Irene Wanyenya, National Drug Authority
Mr. Issa Katwesigye, Ministry of Agriculture, Animal Industry and Fisheries
Ms. Jacqueline Kwesiga, Uganda National Bureau of Standards
Dr. Theresa Sengooba, Uganda National Council for Science and Technology

The panel comprised of key biosafety regulatory agencies/mechanisms in Uganda. Panelists described their envisaged role in implementation of the National Biotechnology and Biosafety law in light of their mandates as follows:

Ministry of Agriculture, Animal Industry and Fisheries – MAAIF, Department of Crop Inspection and Certification • Issue import and export permits for GMO seeds for trials. • Monitor confined the conduct of confined field trials and eventually general release of GMOs. • Manage the trans-boundary movement of GMOs.	Ministry of Water and Environment - MWE/ National Environmental Management Authority – NEMA As the National Focal Point for purposes of the Cartagena Protocol on Biosafety for the Convention of Biological Diversity – CBD: • Liaise with the Secretariat of the CBD. • Provide coordinated flow and exchange of information between: ministries, agencies and departments on matters concerning the trans-boundary movement of GMOs; governments through formally approved diplomatic channels; and the Secretariat to the CBD and other international organizations, concerning biotechnology and biosafety. • Receive information from the Competent Authority regarding biotechnology and biosafety matters in Uganda.

Uganda National Council for Science and Technology - UNCST As a competent authority: • Approve the development, testing and use of GMOs in Uganda; • Update and inform the National Focal Point on matters relating to biotechnology and biosafety; • To ensure safety of biotechnology to human health and the environment during development, testing and use of GMOs. • Take necessary measures to avoid adverse effects on the environment, biological diversity, human health and on socio-economic conditions arising from a GMO; • Oversee the work of the National Biosafety Committee (NBC).	Uganda National Bureaus of Standards - UNBS • Develop appropriate standards in regard to GM, such as labeling standards, packaging, etc. • Build analytical capacity (food and safety assessment, composition analysis, nutritional analysis) food and feed safety for GM based food. • Provide certification services for GM food products.
National Drug Authority In regard to GM-based drugs: • develop and regulate pharmacies and use of drugs in the country; • control the importation, exportation and sale of pharmaceuticals; • control the quality of drugs; • promote and control local production of essential drugs; • encourage research and development of herbal medicines; • establish and revise professional guidelines and disseminate information to the health professionals and the public; • provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the National Drug Policy	Institutional Biosafety Committee - National Agricultural Research Organization • Approve laboratory experiments and contained testing; • Regularly review, monitor and supervise laboratory experiments, contained testing and confined testing; • Make recommendations to the Competent in respect of applications for confined testing and general release; • Ensure that research is conducted in accordance with this national legislation. • Periodically report to the Competent Authority on their activities

SESSION 6: CLOSING PLENARY OF THE FORUM

7.1 Key Issues and Recommendations from the Biosafety Forum 2017

Opening plenary

- Ministry of Science, Technology and Innovation and UNCST committed themselves to host the Biosafety forum annually as a mechanism for accountability of Biosafety in the Country .
- Absence of the National Biotechnology & Bio Safety law constrains the optimal operations of the National Biotechnology Committee (NBC).
- The over 75 Ugandans who have served on the NBC since inception in 1996, and constitute the country's Biosafety human resource capacity which should be both documented and harnessed.
- There is Political will (e.g., by the President, supportive S&T Committee of Parliament, a Ministry of Science, Technology and Innovation, etc.) and experienced scientists who are committed and result-oriented and impactful research. The law is the only barrier to accelerated biotechnology applications to development.
- There is need to develop a comprehensive communication strategy for biotechnology and biosafety, translated in key local languages

Matters arising	Recommendations
Global Biosafety trends and Uganda's readiness for environmental release of GM crops • Uganda has a Policy, institutions and reasonable infrastructural capacity to handle release of GMOs. • The human resource capacity has been built over time; both research and academic programs are in place to build it further in higher education and research institutions. • The Brazilian biosafety system transformed over the last 2 decades and they are reaping great economic benefits. A key lesson from Brazil is that the MARKET dictates the final decisions on commercial release of GMOs. • At Regional level, the integration of Biosafety has been slow but steady as different countries move towards developing domesticated Biosafety systems. However countries like Ethiopia and Nigeria have made significant progress because of the political will of their governments.	• All relevant stakeholders should participate in the designing of a legal framework for biosafety if it is to be successful. • Procedural details such as guidelines or standard operating procedures (SOPs) should not be embedded in the law, but left to the National Authority to regulate. This keeps the law clean and streamlined and allows a fast updating of normative resolutions or guidelines. • Any decision on GMO biosafety, at the national level, must be kept into a single institution. • The MARKET should be given an opportunity to dictate whether/not a GM product is good. "There is no better judge." • The law should be clear on how decisions should be made on biosafety issues. No single institution or person should make, block or reverse a decision. • Regulators of biosafety should never adopt a moratorium, at any level, even for precautionary reasons. They should instead carry out risk assessments, science-based decisions or learn from the experiences of other countries.

Matters arising	Recommendations
• Uganda is making progress in implementing decisions of Cancun COPMOP negotiations, however some outstanding action areas include: o The perennial inadequate representation by officers from relevant government ministries, departments or agencies. o Pending adoption of National Biotechnology Biosafety law. o Compiling and availing of all required information that is pertinent to biosafety to the Biosafety clearing house. o Building sufficient human and infrastructural capacity for Risk Assessment, Management and monitoring of release of GMOs. • Given the socio-economic ramifications of biosafety, Uganda's regulators unlike Brazil, cannot afford to ignore the non-biological aspects of Biosafety. NBC prioritizes the socio-economic aspects of biosafety and will not delegate this role of the Committee to another entity. • On the question of what happens to the products of successful CFTs given that researchers are not yet permitted to conduct general releases, Scientists reported that the information is shared with other countries, for example, on the basis of Uganda's findings with WEMA crop resources, Kenya authorized the environmental release of GM maize. • Participants agreed that although it may be difficult of judge whether or not the country has accumulated the required critical mass to be able to do environmental release of GM crops, the country has and continues to build the capacity in the critical areas of risk assessment and risk management.	• Risk assessment is a robust process and once used as the basis for a comprehensive regulation leads to consistent results for GM plants as well as for other GMOs • The Cartagena Protocol texts should not be literally embedded in any national GMO regulatory framework given that they tend to focus on trans-boundary movement of GMO and NOT the national affairs. • The definition of terms in national legislation and the Cartagena Protocol should be harmonized, for example, the interchangeable use of the terms GMOs and LMOs. • Regulators should not postpone decision-making in regard to biosafety altogether because there is no law as yet. The existing capacities should be harnessed to make sound science-based decisions, and then the precautionary principle may be deployed to defer action in circumstances where there is inadequate capacity to assess a biosafety application.

Matters arising	Recommendations
• Is Uganda ready to protect indigenous varieties following the introduction of GM crops? Yes, Uganda is ready to protect indigenous varieties and there are efforts in NARO to protect indigenous plant and animal germplasm. However this is still quite slow because of resource constraints. The Plant Genetic Resources Research Centre has to date preserved only 5% of our important crops (indigenous varieties). Emerging Gene techniques and implications for biosafety regulation • In regard to whether there are there known ecological and biodiversity threats on release of biologically modified mosquitoes (Anopheles gambie), in principle, it should only be any organism that exclusively feeds on Anopheles gambie. However in nature there is no known organism that feeds exclusively on Anophelese gambie. Further to this, not every species removed from the ecosystem leads to its destruction. Every year a species disappears naturally and the ecosystem does not collapse. • The main criticism for gene editing is the fear of going off-target or having the modification going wrong. • Synthetic biology concern is that these can't be subjected to risk assessment because they are mutant organisms and not GMOs. • Can gene editing be deployed to deal with the challenge of sickle cell anemia? • Concern was expressed that given that gene editing can be done so easily, Uganda may not have the capacity for monitoring its safe deployment. • The presenter's proposal to disregard regulation of synthetic biology was a matter of concern for Ugandan participants.	• Environmental risk assessment should always be carried out before any GM organism is released to the environment.

Matters arising	Recommendations
• Concern was expressed over the potential competition synthetic biology products with especially genetic resources in which Uganda has competitive advantage. • Participants were concerned that it might be difficult to monitor and manage trans-boundary movement GM mosquitoes during the proposed malaria control studies. Status of GM Crop research in Uganda • The meeting observed that that there are very many useful technologies in the public domain whose patents have expired; unfortunately, Ugandan researchers have not exploited them. • Participants were informed that the UNCST IP office had access to global databases were all the information on status of patents and more could be obtained. This resource is available for public use. • The scientists confirmed that they take the agro-ecological zoning of Uganda into consideration when selecting the locations for CFTs of specific crops. Uganda's efforts towards a fully-fledged Biosafety regulatory system • The draft Bill was observed to focus on GMOs, and yet the scope of biosafety should be wider. How are all other non-agricultural biotechnology matters and products going to be regulated? • It was clarified that they are many existing laws to regulate aspects of biotechnology within existing sectoral laws such as the NDA Act, etc. • There was concern about the misinformation about biotechnology and biosafety issues that still persists among the public, including some members of parliament.	• Scientists were cautioned to be realistic when articulating the potential and benefits of biotechnology. It is important for the population to know that the application of biotechnology works in complementarity with for example in agriculture - good agronomic practices. Development of GM products for general release entails an elaborate process of experiments and regulatory procedures. Sensitization programs should therefore bear all this in mind and avoid creating an impression that "biotechnology is a magic bullet that can address all the country's economic challenges.

• How are the lead stakeholders planning to deal with misinformation? In the short term, misinformation will be dealt with through strategic outreach in partnership with the media. • The government will in future consider the option of litigating against persons who deliberately misinform that public. • The draft Bill provides for prosecution of such culprits. • One of the most contentious issues in the draft Bill is the role of UNCST as promoter and regulator of biotechnology, if they maintain their role of Competent Authority.	

7.2 Closing remarks by Hon.Eng. Kafeero Sekitoleko, Chairman, Parliamentary Committee on Science and Technology, Parliament of Uganda.

Hon. Sekitoleko thanked the Minister and the scientists for the efforts made towards building Uganda's biotechnology and biosafety capacity. He reiterated Government of Uganda's commitment to supporting these efforts and assured the meeting that the Parliamentary Committee for S&T was working closely with government to ensure that the draft National Biotechnology and Biosafety Bill was passed into law in the shortest time possible.

He however highlighted the need to strengthen the biosafety capacity of relevant institutions. He observed the need to intensify public education efforts as a means of dealing with the main challenge of the general public's cautiousness in regard to especially agricultural biotechnology. Hon. Sekitoleko recommended that a framework should be in place for regular provision of information about biotechnology – basic information materials should be developed that talk about the technology itself and provide updates on what is being done in Uganda in terms of strengthening capacities for biosafety as well as ongoing activities such as CFTs. He outlined some of the frequently asked questions the members of parliament have encountered in the course of their engagement with the public on biotechnology matters.

In conclusion Hon. Sekitoleko informed the meeting that the Parliamentary Committee on S&T was scheduled to implement nationwide consultations and benchmarking visits in regard to biotechnology and requested for stakeholders' support in this regard.

Annex 1: Programme

	Time	Event	Responsible person
Day one -1st Feb 2017			
	12:00–12:30pm	Arrival and Registration	UNCST
	12:30-1:30 pm	Lunch	UNCST
	1:30-2:00pm	Welcome remarks: Executive Secretary, UNCST Chair, NBC Chairperson, UNCST Remarks by Chief Guest: Hon Minister of Science and Technology and Innovation	Dr. Maxwell Otim Onapa
	2:00-2:40pm	Session 2: GLOBAL BIOSAFETY TRENDS AND UGANDA'S READINESS FOR ENVIRONMENTAL RELEASE OF GM CROPS. Chair: Prof. John Opuda-Asibo	
	2:40-2:55 pm 2:55-3:10pm	**Keynote Address:** **Emerging Global Trends and best practices in Biosafety Regulation in Latin America: what lessons are we learning?**	Prof. Paulo Paes de Andrade
	3:10-3:25pm	Regional commitments and actions in Biosafety Regulation: Is Africa moving forward?	Dr. Woldyesus Sinebo
	3.25-3.45pm	Highlights of the Decisions of the Cancun COPMOP negotiations.	Dr. David Hafashimana
	3:45-4:20pm	Status of capacity development for Biosafety Regulation.	Mr. Herbert Oloka
	4:20-4:45pm	Uganda's readiness for environmental release of GM plants	Dr. Barbara Zawedde
		Discussion	
		Tea/Coffee Break	UNCST
Day 2- 2nd February 2017			
Session 3: EMERGING GENE TECHNIQUES AND IMPLICATIONS FOR BIOSAFETY REGULATION. Chair: Dr. Yona Baguma			

	Time	Event	Responsible person
	9.00-9.20am	Recent advances and controversies with gene editing techniques	Prof. Paulo Paes de Andrade
	9.20-9:30am	Rice improvement approach with CRISPR/ Cas9 Technology	Dr. Jimmy Lamo
	9:30-9:45am	Recent advances in gene drive research in mosquitoes and Malaria control	Dr. Jonathan Kayondo
	9:45-9:55am	Synthetic Biology: What is in it for Africa and Uganda?	Dr. Andrew Kiggundu
	9:55-10.20am	Discussion	
	10:20-10:30am	Tea/Coffee Break	**UNCST**
Session 4: STATUS OF GM CROP RESEARCH IN UGANDA **Chair: Prof. John Enyaru**			
	10:30-10:45am	Efforts towards development of genetically enhanced Vitamin A banana	Dr. Jerome Kubiriba
	10:45-11:00am	Progress made towards developing disease-resistant banana	Dr. Jerome Kubiriba
	11:00-11:15am	Are we ready for climate change? Efforts towards development of drought tolerant maize	Dr. Godfrey Asea
	11.15-11:30am	GM Cassava resistant to CBSD research in Uganda	Dr. Titus Alicai
	11:30- 11:50am	Discussion	
	Session 4 continued Chair: Dr. Clovice Kankya		
	11:50-12:05pm	Off patent GM technologies: a case for Herbicide-tolerant Soybean in Uganda	Dr. Phinehas Tukamuhabwa
	12:05-12:20pm	Progress made in the development of GM disease-resistant potato: what does this mean for farmers, traders, consumers, going forward?	Jimmy Lamo
	12:20-1:10pm	Discussion	
	1:10-1:45pm	Lunch	UNCST
SESSION 5: UGANDA'S EFFORTS TOWARDS A FULLY-FLEDGED BIOSAFETY REGULATORY SYSTEM Chair: Dr. Charles Mugoya			
	1:45-2:45pm	Presentation of the National Biosafety and Biotechnology Bill, 2012 with highlights on the progress, trends and challenges towards the enactment into law.	Ms. Harriet Ityang
	2:45-3:00pm	Policy outreach on Biosafety	Ms. Grace P. Lonyo
	3:00-3:20pm	Discussion	
	3:20-3:40pm	Tea/Coffee Break	**Beth/Eliza**

	Time	Event	Responsible person
SESSION 5: PANEL DISCUSSION AND CLOSING **Moderators: Dr. Charles Mugoya and Dr. Sarah Ssali**			
	3:40-4:20pm	Round table on a coordinated framework for GM Food Regulation: focus on institutional roles in Biosafety Regulation	NDA, UNCST, MAAIF, UNBS, MWE, IBCs
	4:20-4:40pm	Way Forward by	Dr. Maxwell Otim Onapa, UNCST
	4:40-5:00pm	Closing Remarks	Hon. Kafeero Sekitoleko, S&T Committee of Parliament

Annex 2: List of Participants

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Annex 3: Abstracts

1. IMPROVEMENT FOR BACTERIAL LEAF BLIGHT DISEASE RESISTANCE IN RICE USING THE GENE EDITING TECHNIQUES.

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Management of Xanthomonas oryzae pv. oryzae (Xoo), the causal agent of bacterial blight of rice has frequently challenged scientist since the time the new high yielding IR rice series were developed and deployed in the 1960. Several race specific genes have broken down to this pathogen because the pathogen adapts rapidly to changes in host genotypes. In order to hasten the race to develop durable resistance, a new technique has been successfully employed. The modified CRISPR (clustered regularly interspaced short palindromic repeats) systems, comprising single guide RNAs (sgRNAs) and Cas9 endonucleases was employed to bridge the basic and applied rice science by undertaking precise genetic alterations within any genome of interest, the genome editing. The Cas9/sgRNA system is suitable for targeted gene mutagenesis in rice. Lines of T0 generation carrying site-specific mutations were produced at higher frequency than the once generated using carriers, in the traditional transgenic rice development. New lines have been developed ready for testing with potential collaborators.
Key words: CRISPR, Xanthomonas oryzae pv. Oryzae, RNAs

2. RECENT ADVANCES IN GENE DRIVE RESEARCH; USES, RISKS, BENEFITS; THE CASE OF MOSQUITO CONTROL.

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Gene drives are biological systems that increase transmission of genetic traits into a disproportionate fraction of the organism's progeny and hence increasing the odds that they will spread through populations are a natural phenomenon. They could be harnessed for control applications against mosquito disease vectors. This is now becoming a reality thanks to several technological breakthroughs over the years. Among mosquito research, the most advanced developments are those focused on vector-targeted malaria control where various candidate target effector genes, involved in reproduction, and parasite resistance, have been identified; and synthetic genome editing/and drive systems e.g. homing endonucleases, TALENs, CRISPR/Cas9 nucleases have been engineered. Laboratory progress has been promising warranting strategic thinking about preparations for the next steps - i.e., open field trials. While potentially very beneficial, there are risks associated with gene drive research and applications that need to be considered, especially unintended effects on human/animal health or environment. A paramount issue is public acceptance of this novel approach. Experts recommend step-wise research/product development pathways, broad public engagement, robust regulatory and policy frameworks to direct and govern safe and

responsible development of this novel application. However, each application is going to have to be considered on its own merit.

Keywords: Gene drive, Synthetic gene drives, Engineered gene drives, mosquito control, Malaria

3. GENETIC IMPROVEMENT OF COOKING BANANAS FOR HIGH LEVELS OF PRO-VITAMIN A.

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Banana is a major staple food crop providing nutrition and income security to more than 70% of the population in Uganda. Hundreds of clones are grown in all regions of the country except in the north-eastern districts of Karamoja due to arid conditions. The most important types contributing to nutrition security are the cooking bananas, locally called 'matooke'. However, 'matooke' varieties (or clones) are deficient in micronutrients particularly pro-vitamin A (PVA) iron and zinc. Developing consumer-acceptable banana cultivars is a major challenge because it is virtually impossible to introgress a new trait into an acceptable cultivar without affecting yield and taste characteristics through a conventional backcrossing programme. Hence we introduced a phytoene synthase gene for enhancing PVA into 'hybrid M9' and 'Nakitembe' cell lines using agrobacterium-mediated transformation system. The gene was isolated from Asupina, a high PVA banana. Transformed cells were selected on kanamycin-supplemented media and regenerated shoots were multiplied and weaned. Plants were tested for presence of the transgene using PCR and positive plants were planted in a confined field trial (CFT).

A total of 356 independent lines of M9 and 70 lines of 'Nakitembe' were planted in the CFT together with non-transformed controls. Of these, 226 transgenic M9 lines have been harvested and fruits analysed for PVA content. In the plant crop, -carotene equivalent (BCE) ranged from 2.35 to 43 g/g DW for M9. The non-transformed M9 controls had an average of 5 g/g DW. So far, 96 lines (42%) attained or exceeded our target of 20 g/g DW, and 4 lines have more than doubled that target. On the other hand, 15 lines of 'Nakitembe' have been harvested and PVA levels quantified by HPLC. Nine (60%) of the harvested lines exceeded the BCE target, with the highest reaching up to 85 g/g DW. Other than the fruit pulp colour which ranges from yellow to orange in high PVA lines, there were no visible phenotypic variation between transgenic lines and controls. These lines hold great potential for sustainable alleviation of vitamin A deficiency in Uganda and neighbouring countries in the Great Lakes Region of Africa where banana is a staple crop.

Keywords: biofortification, -carotene, confined field trial, transformation, vitamin A deficiency

4. DEVELOPMENT OF RNAi-MEDIATED CASSAVA BROWN STREAK DISEASE RESISTANT CASSAVA.

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Cassava brown streak disease (CBSD) is the most serious constraint to cassava production in Uganda, and most parts of eastern and central Africa. Losses in eastern Africa are estimated at US$ 750 million annually. CBSD is caused by two +ssRNA viruses; Ugandan cassava brown streak virus (UCBSV) and Cassava brown streak virus (CBSV), collectively referred to as cassava brown streak viruses (CBSVs). The CBSVs can infect cassava as mixed infections and are transmitted by whiteflies. Currently, there are no varieties with high levels of resistance to CBSD. The best varieties available are only tolerant to CBSD, and rapidly degenerate under high disease pressure within 2-3 vegetative cropping cycles. A genetic construct in which near full length virus coat protein (CP) sequences were fused in tandem (construct p5001) was transformed into the Ugandan farmer preferred cultivar TME 204. Twenty five (25) independent transgenic p5001 lines of TME204 were initially evaluated for CBSD resistance alongside 5 non-transgenic controls in the field at Namulonge, Uganda. The non-transgenic TME 204 control plants developed foliar and storage root symptoms at 96-100% incidences by 12 months after planting. In contrast, 16 out of the 25 p5001 transgenic lines showed no foliar symptom, less than 10% incidence of storage root necrosis and had >95% usable roots. Eleven (11) p5001 TME 204 lines had <5% incidence of storage root necrosis. There was a direct correlation between level of CBSD resistance and siRNA expression level. In a subsequent trial established with cuttings from 11 best performing p5001 lines, all transgenic lines remained asymptomatic of CBSD, while 98% of the non-transgenic TME 204 controls developed CBSD symptoms in the storage roots. The CBSD-tolerant varieties NASE 3 and NASE 14 included in the trial had >80% root necrosis incidence. Similar high levels of resistance to CBSD in p5001 TME 204 lines were observed in subsequent field trials with subsets of the initial 25 lines at Serere (11 lines) and Mtwapa in Kenya (19 lines). These results demonstrate very high levels of resistance to CBSD conferred by the p5001 construct across locations and vegetative cropping cycles. However, all the transgenic lines were observed to be susceptible to cassava mosaic disease (CMD), a phenomenon later attributed to passage of TME type varieties through somatic embryogenesis. In light of this challenge, two product pathways have been adopted; (a) conventional breeding to cross elite p5001 TME 204 lines with CMD resistant varieties, (b) genetic transformation of non-TME type varieties (NASE 13 and NASE 14) with p5001 construct. Work using these two approaches is in progress and will be highlighted.

Key words: Cassava brown streak disease, Field-based resistance, RNA interference; Cassava brown streak viruses

5. CONFINED FIELD TRIAL EVALUATION OF TRANSGENIC BANANA ENGINEERED FOR NEMATODE RESISTANCE

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Banana parasitic nematodes cause severe root damage and subsequent plant toppling that often leads to 100% yield loss. The perennial nature of banana that is continuously associated with nematodes over a long period presents a major problem for control by the farmers. Nematodes also persist in the soil for quite a long period therefore immediate replanting of previously infested fields is no feasible option. Resistant varieties have the potential for sustainable and cost-effective control for banana parasitic nematodes. Conventional breeding of banana for nematode resistance is quite limited because of inherent barriers to genetic improvement of the crop. The genetic engineering approach was therefore utilized to develop transgenic resistance in bananas of cultivar Sukali Ndizi expressing single or double combinations of anti-nematode transgenes driven by constitutive CaMV35S or maize ubiquitin promoters.

The anti-nematode transgenes expressed in banana were 1) the modified rice (OcI D86) cystatin, 2) the potato aspartic protease inhibitor (PDI), and 3) the nematode repellent peptide. The transgenic bananas expressing these transgenes were then evaluated at NARL, Kawanda under screen house conditions. The best performing line selections were advanced for testing in the first confined field trial (CFT) where nematode selection pressure was optimized to facilitate identification of those lines with resistance that confers 70% to 100% protection levels against nematodes. In preliminary confined field trial for proof of concept, 12 transgenic selections expressing single or dual anti-nematode transgenes provided more than 90% resistance. The 12 lines were bulked and an extended, replicated CFT was planted in April 2016 to confirm performance of the promising technologies over at least two crop cycles as well as the impact of technology on the environment. All the biosafety requirements are being strictly adhered to at all stages during development and evaluation of these transgenic bananas.

Keywords: Transgenic banana, parasitic nematodes, confined field trial, transgenic banana

6. PROGRESS MADE ON GM RICE EFFICIENT IN NITROGEN AND WATER USE IN UGANDA.

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Rice farmers in Uganda, like most farmers in sub-Saharan Africa, face huge production challenges among which decreasing soil fertility and drought stress are key. Development of drought tolerant and nitrogen use efficient rice varieties using conventional breeding is difficult due to limited/non-existence of major genes that can be used in conventional genes. In this report, progress made to address low soil nitrogen and drought stress in upland rice production in Uganda using transgenic approach is presented. NERICA4 (New Rice for Africa) rice lines over-expressing barley alanine amino transferase (HvAlaAT) under the control of a rice stress-inducible promoter (OsAnt1) were evaluated. The result of field evaluations over three growing seasons at Namulonge (NaCRRI) with three nitrogen levels (30, 60 and 90 kg N/ha) revealed that grain yield of OsAnt1:HvAlaAT lines was significantly higher than wild type and null sibling controls under different N application rates. Our field results clearly demonstrated that this gene insertion can significantly increase the dry biomass and grain yield compared to controls under low N supply. This observation could guide breeding for improved efficiency of nitrogen use in rice low fertile soils.

Keywords: NERICA-4, biomass, wild type, alanine amino transferase

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