10TH ANNUAL NATIONAL BIOSAFETY CONFERENCE

2nd - 5th November, 2021

Theme: *"A Decade of Biosafety Regulatory Excellence: Experiences and Lessons"*

PROGRAMME AND BOOK OF ABSTRACTS

Organised by:

NATIONAL BIOSAFETY AUTHORITY

Championing for a Biosafe Nation

10TH ANNUAL NATIONAL BIOSAFETY CONFERENCE

2nd - 5th November, 2021

Theme: ***"A Decade of Biosafety Regulatory Excellence: Experiences and Lessons"***

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REPUBLIC OF KENYA

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NATIONAL BIOSAFETY AUTHORITY

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THE 10TH ANNUAL BIOSAFETY CONFERENCE

Theme: "A Decade of Biosafety Regulatory Excellence: Experiences and Lessons"

DATE: 2ND – 5TH NOVEMBER 2021

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BAYER

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AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY

AATF PROSPERITY THROUGH TECHNOLOGY

NRF KENYA

The conference opening will be presided over by the Chief Guest, Prof. George Magoha, Cabinet Secretary for Ministry of Education on 4th November 2021 at 9.00 am

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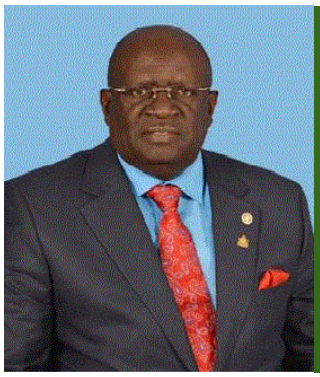
STEERING AND SCIENTIFIC PROGRAMMES COMMITTEE

NAME	TITLE
1. Prof. Dorington Ogoyi	Chairman/CEO
2. Dr. Roy Mugiira	Director, Technical Services
3. Josphat Muchiri	Deputy Director Technical Services
4. Julia Njagi	Assistant Director Technical Service (CED)
5. Nehemiah Ng'etich	Assistant Director Technical Service (BTAD)
6. Anne Muia	Senior Biosafety Officer
7. Esther Njeri	Assistant Director Finance
8. Pauline Kilonzo	Senior Supply Chain Management Officer
9. Brian Abook	Senior Communications Officer
10. Irene Kamau	Senior ICT Officer
11. Doreen Muthoni	Senior Human Resource Officer

MESSAGE FROM THE CABINET SECRETARY, MINISTRY OF EDUCATION



It is my greatest pleasure to be with you to preside the opening of the 10th Annual Biosafety Conference. The event is significant in accelerating Kenya's long-term development plan, the Kenya Vision 2030 and the Big Four Agenda.

This event has come when, as a nation, we need to evaluate our achievements towards attaining our Country's development agenda sustainably. In this case, the primary focus is on how various government entities work together to deliver the Government's brainchild - the Big Four Agenda.

As we are all aware, the 'Big Four Agenda' focuses on Universal Health Coverage, Quality and affordable housing; Food security to all Kenyans; and Manufacturing. The focus is on improving the living standards of Kenyans, growing the economy and leaving a lasting legacy by 2022. The projects directly relate to Kenya's Vision 2030.

Today, after a decade of biosafety regulatory excellence, I commend the National Biosafety Authority for approving the Bt-cotton for Environmental Release. I am aware that this will result in high yields in Cotton, thus putting the nation at the forefront in textile production in Africa and the world. Furthermore, it will enhance Kenya's apparel production industry, a significant milestone in attaining Manufacturing as one of the Big Four Agenda items.

The Authority also approved BT maize for National Performance Trials (NPTs). Once available to our farmers, this genetically modified maize variety will significantly improve food security in Kenya, reduce environmental damage, and help smallholder farmers achieve significant gains in their earnings.

About four months ago, the Authority approved the application for the environmental release of genetically modified (GM) cassava. We are delighted that through this GM Cassava, farmers will be protected from devastating losses caused by cassava diseases. In addition, together with consumers, farmers will benefit from increased cassava root quality and marketable yield.

The three interventions that I have mentioned will significantly contribute to addressing Food Security and Nutrition, and Manufacturing by promoting value addition and opening up employment opportunities to Kenyans.

Again, the development and subsequent approval of the GM Cassava for National Performance Trials indicate that Kenya can develop homegrown biotechnology products. Our scientists are doing an excellent job making us visible across the globe through innovations in biotechnology. This would not have been possible without the facilitation of the National Biosafety Authority as a regulatory agency for the technology. Now, Kenya is part of

the few African countries that are progressively developing biotechnology products, thereby slowly drifting away from being recipients of technology developed elsewhere.

Many African states cannot harness the full potential of biotechnology crops and products because of the weak capacity to regulate biotechnology crops and products. Kenya has not been spared either. I am conscious of our nation's key challenges, especially regarding the relevant regulations that govern GM products.

Kenya needs biosafety, which goes hand in hand with biotechnology. Yet, as mentioned earlier by the Board Chair, we face regulatory challenges in adapting to new and emerging technologies. I have taken note of these challenges, including the Government ban on importation of GM foods and the overlaps in regulatory mandates. I undertake to address this with Cabinet colleagues as appropriate.

As a Ministry, we will try our best towards working with the parliament in ensuring that Kenya obtains a harmonized regional biosafety regulatory framework. We will also explore a co-evolutionary approach in which a particular technology is developed alongside its regulatory framework.

As the stakeholders, this Conference presents an opportunity of looking at the experiences and lessons learnt during the decade of Biosafety Regulatory Excellence in Kenya.

PROF. GEORGE MAGOHA,
CABINET SECRETARY, MINISTRY OF EDUCATION

MESSAGE FROM THE CHAIR, NATIONAL BIOSAFETY AUTHORITY BOARD

As the Chairman of the National Biosafety Authority Board, I have the honour to welcome you on behalf of the Authority to the 10th Annual Biosafety Conference.

I am delighted to acknowledge the presence of our Cabinet Secretary, Ministry of Education, Prof George Magoha and other high-level participants and delegates joining us physically and virtually. I would also like to warmly welcome representatives from civil society, the scientific community, the business sector, and other stakeholder groups today.

In the same breath, I would like to register my sincere appreciation to the Government, through the Ministry of Education, for supporting the Authority in hosting the 10th Annual Biosafety Conference.

Special gratitude goes to this year's key sponsors, namely; CORTEVA, Bayer, Crop Science, African Union Development Agency (AUDA-NEPAD), African Agricultural Technology Foundation (AATF), Program for Biosafety Systems (PBS), CIMMYT and the National Research Fund (NRF), who are also here with us. We sincerely appreciate our partners who supported us over the years and look forward to a prosperous future together.

For the last ten years, the Authority has positioned itself strategically in its operational environment by aligning itself effectively to the changes taking place in biotechnology. Thanks to this, the Authority has remained relevant while enhancing its performance, meeting diverse expectations and aligning programmes and activities to the overall Government development agenda - the Kenya Vision 2030 and the Big Four agenda.

Consequently, NBA has made outstanding achievements over the ten years of our operation. The most notable ones that I am pleased to inform you about are;

1. The approval of BT Cotton for Environmental release; this genetically modified cotton variety is resistant to the African Bollworm. Reliable quality cotton production will increase the utilization of cotton lint, cottonseed oil and seed cake along the value chain. In addition, it will promote Kenyan businesses, provide employment for women and youth and play a role in addressing food security and Manufacturing, which is part of the Big 4 Agenda.
2. The approval of BT maize for National Performance Trials (NPTs); this approved genetically modified maize variety is resistant to the African Stem Borer and the Fall Army Worm. The variety will significantly improve food security in Kenya, reduce environmental damage due to the minimal use of pesticides and help smallholder farmers achieve significant earnings.

3. The approval of genetically modified (GM) cassava; this improved cassava is resistant to Cassava Brown Streak Disease (CBSD). Kenyan farmers will benefit from increased cassava root quality and marketable yield. In addition, an increase in cassava yields will address Food Security and Nutrition, and Manufacturing at the value chain addition.
4. The establishment and operationalization of regional offices in Mombasa, Namanga, JKIA, and Busia. We aim to open more border offices.
5. Transitioning from ISO 9001:2008 to ISO 9001:2015

The outstanding achievements I have highlighted have not come without challenges. Some of the most notable challenges are;

1. The Government ban on importation and use of GM foods that hampers the implementation of the Biosafety Act, 2009.
2. The regulatory challenges in adapting to new and emerging technologies. The challenge in accessing innovations in biotechnology in Africa is often not so much the capacity to utilize the technology but the lack of capacity to regulate the technology. Modern biotechnology requires technical competence, infrastructure, and institutional capacities to use, manage and regulate.

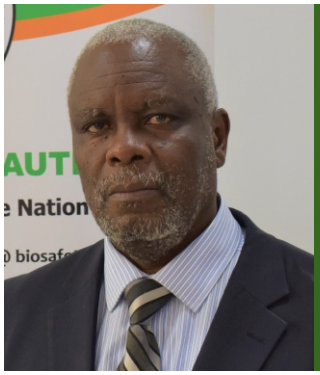
Lastly, the misinformation of the public due to fast and widespread fake news.

This Conference builds on the experiences and lessons learnt during the ten-year period the National Biosafety Authority has been in operation. Participation in this Conference thus carries an important responsibility.

We are privileged to have in attendance so many distinguished experts and Resource persons. I am confident that their knowledge, experience, and expertise will provide essential insights into strengthening mechanisms to promote biosafety awareness and regulations in Kenya.

DR. JOSEPH CHAVUTIA,
CHAIR, NATIONAL BIOSAFETY AUTHORITY BOARD

MESSAGE FROM THE CHIEF EXECUTIVE OFFICER, NATIONAL BIOSAFETY AUTHORITY



I am delighted to be here today for the opening of this Conference. First, let me take the opportunity to welcome you to the 10th Annual Biosafety Conference.

With the theme: "A Decade of Biosafety Regulatory Excellence: Experiences and Lessons", the Conference provides a prime forum for us to celebrate a decade of excellence in Kenya's biosafety regulation. We will also get the chance to share experiences and collect lessons to enhance efficiency in the National Biosafety Regulatory Framework.

This Conference has attracted delegates from all over the world, people with wide-ranging knowledge on biotechnology and biosafety related matters. I thank you all for creating time to be with us to share your knowledge and vast experiences.

The National Biosafety Authority (NBA) was established pursuant to the recommendations of the National Biotechnology Development Policy of 2006 and subsequent enactment of the Biosafety Act No. 2 of 2009. The mandate of NBA is to exercise general supervision and control over the development, transfer, handling and use of Genetically Modified Organisms (GMOs) so as to ensure safety of human and animal health and provide adequate protection of the environment. The objectives of the Biosafety Act, 2009 as spelt out in the Act include:

- To facilitate responsible research into and minimize the risks that may be posed by GMOs
- To ensure an adequate level of protection for safe transfer, handling and use of GMOs that may have an adverse effect on the health of the people and the environment
- To establish a transparent, science-based and predictable process for reviewing and making decisions on transfer, handling and use of GMOs

Since its establishment in 2010, the Authority has strived to deliver on its mandate by ensuring that the Country has a functional Biosafety regulatory framework as envisaged in the Act.

Under the Biosafety regulatory framework in the Country, many research projects have been carried out towards improving crops and animals to address constraints in productivity. To date, the Authority has approved 37 laboratory and 14 confined field trial GMO projects undertaken in various research and academic institutions in the Country. Regarding commercialization, Bt cotton modified for insect resistance is already with the farmers, while Bt maize and GM cassava are in the final phase of being availed to the farmers for cultivation.

Worldwide, there is an increase in demand for food, and biotechnology is one tool that enhances agricultural production. Consequently, many countries adopt biotech crops to boost food security even though the regulatory approaches vary from Country to Country.

As a result, we organized the 10th Annual Biosafety Conference to celebrate a decade of Biosafety Regulatory Excellence while dissecting the experiences and lessons and promoting public awareness and public participation on biosafety matters.

Unlike last year's virtual Conference, we have a hybrid conference thanks to the COVID -19 situation this year. The Conference will run from 4th - 5th November 2021, opening with a keynote address on the "***Evolution of Biosafety Systems in Kenya and Africa***", followed by discussions on four thematic areas, namely;

i. Science, Technology & Innovation Agenda, and Biosafety regulatory frameworks in Kenya;
ii. Advances in emerging technologies;
iii. Status of Biotechnology research projects in Kenya;
iv. Progress and Roadmap to commercialization of GM cassava in Kenya;

As a reminder, this Conference was preceded by a two-day pre-conference virtual workshop from 2nd to 3rd November 2021. The workshop focused on key emerging trends in biotechnology, biosafety and trade, which include;

i. Introduction and management of Low-Level Presence (LLP) and Adventitious Presence (AP) situations in crops;
ii. Monitoring of commercialized genetically modified crops in Kenya and other countries;
iii. Experiences of regulating gene stack events or multiple gene events from other countries;

I am hopeful and confident that we will make fruitful contributions to the deliberations that will spur the meaningful growth of biotechnology in Kenya.

PROF. DORINGTON OGOYI,
CHIEF EXECUTIVE OFFICER,
NATIONAL BIOSAFETY AUTHORITY

10TH ANNUAL NATIONAL BIOSAFETY CONFERENCE

Theme: *"A Decade of Biosafety Regulatory Excellence: Experiences and Lessons"*

4th – 5th November 2021

Organised by:

NATIONAL BIOSAFETY AUTHORITY

Championing for a Biosafe Nation

PRE-CONFERENCE WORKSHOP ON EMERGING TRENDS IN BIOTECHNOLOGY AND BIOSAFETY REGULATION

Date: 2ND - 3RD November 2021, 13:30- 17:00 (EAT)
Host: National Biosafety Authority

Workshop Programme

Day one: 2nd November 2021 Session Chair: Dr. Roy Mugiira		
Time	**Topic**	**Responsible**
1.30-1.50pm	Welcome Remarks and Workshop Objectives	Prof. Dorington Ogoyi, National Biosafety Authority
Session I: Management of Low Level Presence (LLP) and Adventitious Presence (AP) situation s in Seed, Grain and derived products		
1.50-2.10pm	Introduction to Low Level Presence and Adventitious Presence in Seed, Grain and derived products	Mr. Abed Mathagu, African Agricultural Technology Foundation (AATF)
2.10-2.30pm	Industry perspective and p olicy considerations in LLP and AP situations	Ms. Chantel Arendse, Croplife, South Africa
2.30-2.50pm	Global Approaches and Industry thoughts on LLP	Dr. John McMurdy, Croplife International
2.50--3.10pm	Kenya's proposed regulation of LLP and AP situa tions in in Seed, Grain and derived products	Ms. Ann Muia, National Biosafety Authority
3.10-3.30pm	Discussions of Session 1	All
	BREAK	
Session II: Post commercialization monitoring of GM crops		
3.40-4.00pm	Monitoring of commercialized GM crops in South Africa: experiences and lessons learnt	Dr Julian Jafta , Department of Agriculture, Land Reform and Rural Development, South Africa
4.00 - 4.20pm	Post commercialization monitoring approaches of GM crops, IRM	Jennifer Hubert Croplife, Canada
4.20-4.40pm	Kenya's guidelines on the post release monitoring of GM crops	Mr. Josphat Muchiri, National Biosafety Authority
4.40 - 5.00pm	Discussions of Session 2 Group photo	All
End of Day 1		

Rapporteurs: NBA

Day two: 3rd November 2021 Session Chair: Nehemiah Ngetich		
Session III: Regulation of Stack Gene Events		
Time	**Topic**	**Responsible**
1.40-2.00pm	Introduction to gene stacking, rationale and applications	Dr. Marc Heijde, VIP IPBO, Ghent University
2.20-2.40pm	Regulation of gene stack s in Kenya	Ms. Julia Njagi, National Biosafety Authority
2.40-3.00pm	Discussions of Session 4	
Panel discussion on country experiences on Gene stacking **Moderated by: Prof. Douglas Miano, University of Nairobi**		
3.00-4.10pm	Country experiences on regulation of stacked gene events; Latin, North Americas, Asia (10 minutes) Europe (10 minutes) African Countries (10 minutes)	 Dr. Abby Simmons, Croplife International Dr. Benno Van der Laan, Green Orange Global Mr. Samuel Timpo, African Union Development Agency - NEPAD
4.10-4.25pm	Pre-conference workshop evaluation (online)	ICT, National Biosafety Authority
4.25-4.40pm	Closing remarks	Prof. Dorington Ogoyi, National Biosafety Authority
END OF PRE-CONFERENCE WORKSHOP		

Rapporteurs: NBA

10TH ANNUAL BIOSAFETY CONFERENCE

Dates: 4th - 5th November 2021
Host: National Biosafety Authority
Venue: Lake Naivasha Sawela Lodge

Conference Program

Day one: 4th November 2021		
Session 1: Opening Ceremony Moderator: Dr. Roy B. Mugiira, National Biosafety Authority		
Time	**Topic**	**Responsible**
9.00-10.15am	Welcome Remarks Keynote Address: "Biosafety evolution in Kenya and Africa" Opening Address	Prof. Dorington Ogoyi, CEO, National Biosafety Authority Dr. Jeremy Ouedraogo, Head, African Union Development Agency - NEPAD Dr. Joseph Chavutia , Chair, National Biosafety Authority Board Chief Guest: Prof. George Magoha, Cabinet Secretary, Ministry of Education
10.15-10.45am	Group photo and Tea Break	
Session II: Science, Technology & Innovation Agenda; and Biosafety regulatory frameworks in Kenya Chair of session: Dr. Roselida Owuor		
10.45-11.00am	The Biosafety Regulatory Framework in Kenya	Dr. Roy Mugiira, National Biosafety Authority (NBA)
11.00-11.15am	Role of NACOSTI in the STI Agenda; Biosciences and Biotechnology	Prof. Walter Oyawa, National Commission for Science, Technology & Innovation (NACOSTI)
11.15-11.30am	Funding biotechnology research in Kenya, Challenges and opportunities	Dr. Jemimah Onsare, National Research Fund (NRF)
11.30-11.45am	Role of KENIA in technology innovation s and dissemination	Dr. Tommy Omwansa, Kenya National Innovation Agency (KeNIA)
11.45-12.00pm	Interface between Biotechnology Event Approval and Crop Variety release and Registration - Africa Experience	Dr. Silas Obukosia, African Union Development Agenc y- NEPAD
12.00-12.15pm	Kenya GM crops variety release and seed certification schemes	Prof. Theophilus Mutui, Kenya Plant Health Inspectorate Service (KEPHIS)
12.15-12.30pm	Role of DVS in management and control of animal diseases	Dr. Obadiah Njagi, Directorate of Veterinary Services (DVS)
12.30-1.00pm	Discussions	All
1.00-2.00 pm	Lunch break	
Session III: Advances in emerging technologies Chair of session: Doris Wangari, PBS Kenya		
2.00-2.20pm	Global regulatory approaches in Genome editing: Special f ocus on African countries	Mr. John Komen, Program Biosafety Systems, Africa

2.20-2.40pm	Synthetic Biology – new tools and technologies for accelerating biotechnology	Prof. Paul Freemont, Imperial College London, South Kensington Campus
2.40-3.00pm	Introduction to gene drives and its applications in management of malaria in Africa	Dr. Willy Kibet, Bioconsortium Africa Ltd
3.00-3.20pm	Industry experiences on gene edited crops	Dr. Maria Fedorova, Corteva Agrisciences
3.20-4.00pm	Best approaches to s cience communication of new and emerging biotechnologies	Dr. Margaret Karembu, MBS International Service for the Acquisition of Agri -biotech Applications (ISAAA AfriCenter)
4.00 - 4.20 pm	General discussions	
End of Day 1		

Rapporteurs: NBA

Day two: 5th November 2021		
Session IV:Status of Biotechnology research projects in Kenya **Chair of session: Dr. Silas Obukosia**		
Time	**Topic**	**Responsible**
9.00-9.15am	Registration and roles of Institutional Biosafety Committee Members	Mr. Nehemiah Ngetich, Natio nal Biosafety Authority (NBA)
9.15-9.30am	Status update of Bt maize project in Kenya	Dr. James Karanja, Kenya Agricultural and Livestock Research Organization (KALRO)
9.30-9.45am	Status update of genome edited contained use project (Yam/banana)	Dr. Leena Tripathi, International Institute of Tropical Agriculture (IITA)
9.45-10.00am	Status update of late b light resistance potato project	Dr. Marc Ghislain/ Dr. Eric Magembe International Potato Center (CIP)
10.00-10.15am	Status update of confined field tri al of Rift Valley Fever Project at Kapiti Ranch	Dr. George Warimwe, KEMRI Wellcome Trust
10.15-10.30am	Status update of the contained use research project on African Swine Fever (ASF)	Dr. Lucilla Steinaa, International Livestock Research Institute (ILRI)
10.30-10.45am	Status update of the contained use research project on grass pea	Dr. Sita Ghimire, International Livestock Research Institute (ILRI)
10.45-11.00am	GM Feed Policy in the EU and its implications on Kenya	Priscila Quaini Jacobitz, CropLife, E urope
11.00-11.20am	Discussions	All
11.20 -11.40 am	**Tea Break**	
Session V: Progress and Roadmap to commercialization of GM cassava in Kenya **Session Chair: Ms. Bibiana Iraki, ISAAA**		
11.40 -1.00pm	**Panelists;** • Dr. Catherine Taracha (KALRO) • Prof. Douglas Miano (UoN) • Dr. Roy Mugiira, NBA • Mr. James Muthee, KEPHIS • Ms. Catherine Otaga, Cassava value chain expert ***Guided discussions***	**Moderator:** Ms. Bibiana Iraki, International Service for the Acquisition of Agri -biotech Applications (ISAAA AfriCenter)
	Closing ceremony, Moderated by Ms. Ann Karimi, NBA	
1.00-1.10pm	Conference Evaluation	ICT, National Biosafety Authority
1.10-1.30pm	Vote of Thanks	Mr. Archibald Munyi, NBA Board member
	Closing Remarks	Prof. Dorington Ogoyi, CEO, Dr. Joseph Chavutia, Chair NBA Board
END OF CONFERENCE		

Rapporteurs: NBA

PRE-CONFERENCE ABSTRACTS

SESSION 1: Management of Low Level Presence (LLP) and Adventitious presence (AP) situations in seed, Grain and derived products

Introduction to Low Level Presence and Adventitious presence in seed, grain and derived products

Mr. Abed Mathagu
African Agricultural Technology Foundation (AATF), Nairobi, Kenya

Abstract

Codex Alimentarius Commission developed guidelines for risk assessment of foods derived from modern biotechnology. OECD developed similar guidelines for plant varieties. Member countries requested guidance on risk assessment is situations of low- level-presence - LLP due to asynchronous approval of traits in trading partners and likelihood of finding traces of traits approved in one member but not in the other. CODEX developed Annex III in the Plant guideline to help in risk assessment in LLP situations. This guideline is domesticated in Kenya but the threshold was not yet determined. Kenyans Biosafety Act provides a threshold for labelling at 1% of the total weight. LLP can occur in low levels beyond or below the labelling threshold but yet significant to warrant risk assessment. For instance, 5% presence which is low enough would be declared as… may contain 5% r-DNA ingredients because it is above the labelling threshold of 1%. International commodity trade has never taken place at a purity level of 100%. Even certified seed is sold at a purity level of 99% and has, in the past been adversely affected by the LLP and AP. In 2006 and 2009, traces of Herculex R corn and GM flax were detected in exports to the EU leading to trade disruption. Tremendous resources and inland testing capability are therefore required to implement stringent LLP/ AP requirements. In South Africa consignments are only regarded as non-GMO they it contains less than 1.0% total GMO. In the European Union, LLP is set at the lowest LOD and lowest LOQ detectable level at 0.1%. In Kenya, conventional seed production laboratory purity standards permit trace 0.1 to 1% while the Seed Industry best practice for breeder's and pre-basic (pre-foundation) seed are at 0%, basic (foundation) seed at 0.5% and Genetic purity basic (foundation) seed at ?95%.
Key words: Low level presence, risk assessment, threshold

Industry perspective and policy considerations in LLP and AP situations

Chantel Arendse
CropLife SA

Abstract

The international trade of agricultural products, requires the movement of large volumes of food and feed along the value chain from farms, to storage, handling and shipping at ports, before arriving at consumers where the food is needed. Despite adherence to strict quality management systems, the interconnectedness of seed and grain handling systems may unintentionally result in trace amounts of biotech products in grain and seed shipments that has been approved in the country of production but not in the country of import. This is what is known as Low Level Presence or LLP) and can lead to unnecessary trade disruptions due to shipments being delayed or rejected. The global cultivation of biotech crops is rapidly increasing across the world. Despite the rigorous safety evaluation and experience with biotech crops, regulatory approvals in different countries does not happen at the same time. Furthermore, the lack of policy or inconsistent approaches to manage LLP may negatively impact the trade of agricultural products and keep much needed innovation out of the hands of farmers. As an industry association, CropLife International believes that LLP is manageable through the adoption of practical approaches that give due consideration to safety assessments and decisions taken in other jurisdictions and the application of LLP policies that are realistic, predictable and supportive of a reliable trading system.

Key words: LLP, AP

Global Approaches and Industry thoughts on LLP

Dr. John McMurdy
Croplife International

Abstract

Low Level Presence occurs most often as a result of asynchronous approvals of GM crops between countries and comingling of GM/non-GM grains during the production process. This is ultimately a solveable issue through application of timely approvals for the food, feed and processing uses of new GM products along with thresholds set for not yet approved GM varieties. This presentation will talk about practical solutions, a few global approaches to manage LLP by national governments as well as model policy that can be adopted by governments wishing to minimize trade distruptions that can result from LLP.

Guidelines on managing Low-level presence (LLP) and adventitious presence (AP) of Genetically Modified Organisms in Seed, Grain and derived products in Kenya

Anne Muia
National Biosafety Authority

Abstract

The need to meet growing caloric demands has led to a rapid global adoption of modern Biotechnology to increase agricultural productivity. Approval of GM crops and derived products has not occurred uniformly across the globe and regulatory approaches vary between countries. International trade can be impacted if trace amounts of GM events already approved for commercial use in one country are detected in an importing country that has not yet approved the event. With increasing adoption of GMOs by different countries, asynchrony in product approvals and transboundary movement of seed, grains and derived products from countries that have widely adopted GMOs, it is expected that GM Events, approved in countries of origin elsewhere but not approved in Kenya; may be present in low levels in imported seeds, grains and/or derived products. Additionally, with adoption of GMOs in Kenya, situations may arise where GM events approved in particular varieties may be present at low levels in seeds of different varieties for which they were not approved. Adventitious Presence may arise from non-compliance to established Confined Field Trials (CFT) policies and protocols, accidents or lapses in monitoring and enforcement. These guidelines shall provide a framework for defining how imported and locally produced crops and/ or crop products with low level presence and adventitious presence will be handled in Kenya. In developing the guidelines, consideration was given to all relevant national laws and international standards. These guidelines are facilitative of trade between Kenya and exporting countries while ensuring food, feed, and environmental safety and public confidence.

Key words: Low Level Presence, Adventitious Presence, Safety, International trade

Post commercialization monitoring approaches of GM crops, Insect Resistance Management (IRM)

Dr. Jennifer Hubert
Croplife, Canada

Abstract

Over 20 years after the first introduction of genetically engineered insect resistant traits, there is a clear commitment and momentum to the development and implementation of resistance management best practices across the industry. The federal government currently has oversight of IRM plans which are reviewed as part of the single trait authorization and stack notification process. While the federal government links conditions around post-commercial monitoring to the authorizations, the development and implementation of good stewardship practices on the farm is truly a joint effort by the broad seed sector in Canada. The seed companies and growers are supported by advice from a considerable network of seed industry experts, commodity associations, academics, federal government experts and provincial and private agronomists. Many of these experts meet on a regular basis through the Canadian Corn Pest Coalition, which was formed in 1996. Key resources for growers are available through the platform Manage Resistance Now, which was launched in 2019, with resources on managing resistance to Bt corn added in 2020.

Kenya's guidelines on the post release monitoring of genetically modified crops

Josphat N. Muchiri
National Biosafety Authority

Abstract

The development of a genetically modified organism (GMO) passes through several stages: from initial research and development in the laboratory and subsequent greenhouse testing, both under containment, to confined field trials in the open environment and finally post-release monitoring after the GMO has been placed on the market. The Kenyan Biosafety Act, 2009 and the Biosafety (Environmental release) Regulations, 2011 require that commercialized GMOs (plants, animals and microorganisms) are monitored for an initial ten years and another ten years if the project is renewed. The objective of monitoring is to identify any unanticipated effects of the organism and its use to human, animal health and the environment after placing on the market. It also serves as an early warning system and indicate the need for risk management measures and/or a re-assessment of the released GMO. The monitoring is carried out by applicants issued with permits who are required to submit annual reports to National Biosafety Authority (NBA). Independent monitoring is also carried out by NBA and other regulatory agencies as provided for in the Biosafety Act. Three types of monitoring are anticipated; monitoring for compliance to approval conditions, general monitoring (for all commercialized GMOs) and case specific monitoring (on case by case basis). The NBA through stakeholder engagement has developed a post release monitoring manual to guide applicants on how to conduct the monitoring and report to the Authority to assist in regulatory decisions. The manual provides for monitoring plan, monitoring indicators, selection of monitoring sites, tools for monitoring, frequency of monitoring, data analysis, review of the monitoring plan and recommendations.

Key words: Genetically modified organism, Biosafety Act, compliance, post release monitoring, general monitoring, case specific monitoring

Session III: Regulation of Stack Gene Events

Introduction of gene stacking, rationale and applications

Dr. Marc Heijde
VIB-UGent_International Plant Biotechnology Outreach (IPBO)

Abstract

Gene stacking is a term used in the context of genetically engineered crops, but is not a new idea in plant breeding. Plant breeders have always been stacking genes by making crosses between parents that each have a desired trait and then identifying offspring that have both of these desired traits. The combined traits resulting from this process are called stacked traits. The stacked traits can offer agronomic enhancements to meet the needs of the farmers and consumers. For example, gene stacking in crops allows to reduce the pest or disease resistance breakdown by pyramiding resistance genes with different modes of action. The stacking of genes of the beta-carotene biosynthetic pathway, has for example allowed to create the nutritionally improved golden rice. With biotech crops, the fastest and very simple way to create a stack is by crossing existing plants harboring the desired traits. These are called breeding stacks, in contrast to molecular stacks where new events are created by genetic transformation to integrate the desired traits. The potential and cost of developing these stacks is largely dependent on regulatory obligations. Breeding stacks are the result of a combination of already approved events. Some countries are considering this as new events and thus must pass new assessment whereas other countries will consider that there is no reason for new hazards as compared to the separate events. However, stacking is a broadly and increasingly used breeding technique to provide farmers and consumers with improved products.

Key words: Biotechnology, gene stacking, pyramiding, event

Regulation of Stacked gene events in Kenya

Julia Njagi
National Biosafety Authority

Abstract

Gene stacking of traits can be accomplished mainly through conventional plant breeding, where parents with single GM events are crossed to produce progeny that contain two or more GM events, commonly referred to as "breeding stacks", or by using molecular methods, where two or more traits are simultaneously or sequentially introduced into a host plant. The difference between the two stacking methods is that stacked trait products produced via conventional breeding do not contain a new event(s) that has not been assessed and approved by regulatory authorities. Different approaches have been adopted for the regulation of stacked trait products among various countries. The proposed draft guideline identifies three possible Gene Stack categories, either developed through breeding or molecular techniques as subject to possible regulation by the Authority. These include: GM Stacks where the single events have already been approved, GM stacks where at least one of the events is not approved, or GM Stacks where all the events have not been approved. For GM Stacks where all the single events have previously been approved by the Authority, the applicant will be required to submit a notification to NBA in a prescribed format to assess the adequacy of the Risk Assessment report of the single events. Additionally, a different approval process shall be adopted for GM Stacks where at least one of the single events have not been approved by the Authority as well as in cases where none of the single events have been given prior approval by the Authority.

Key words: GM Stacks, Breeding Stacks, Molecular stacks

Regulatory approaches to stacked trait products in Latin, North Americas, Asia

Dr. Abby Simmons
CropLife International

Abstract

Plants with multiple genetically modified (GM) traits can be created through the crossing of GM parental lines. These stacked trait products produced through conventional breeding, also known as breeding stacks, have become widely used by farmers around the world. Countries across North America, Latin America, and Asia have taken different regulatory approaches to stacked trait products. Many countries note the long history of safety of conventional breeding and recognize that breeding stacks are as safe as other products of conventional breeding. This talk will overview the approaches taken by different countries with a focus on countries that have recently updated or streamlined their approaches to regulating stacks such as Argentina, Brazil, and Japan. Increasingly, we see countries adopting policies that do not require additional experimental data from breeding stacks, as long as the traits are not predicted to interact. Potential interactions between traits are rare and can be predicted based on the mode of action of the individual traits.

Key words: Stacked trait products, breeding stacks, GM, regulations

CONFERENCE ABSTRACTS

SESSION I: Official Opening and Conference Key Note Address

SUMMARY OF KEYNOTE ADDRESS

Building Functional Biosafety Regulatory Systems in Africa- "A Decade of Biosafety Regulatory Excellence: Experiences and Lessons."

Jeremy Tinga Ouedraogo (PhD)
Head/Coordinator AUDA-NEPAD Africa Biosafety Network of Expertise and Integrated Vector Management programmes
Head of AUDA-NEPAD Centre for Rural Resources and Food Systems.
Africa Union Development Agency-NEPAD- Centre for Rural Resources and Food Systems, Senegal, Dakar, Senegal.

Abstract

Policy. The Africa Union Agenda 2063 is fifty-year strategic framework for socio-economic development of the 55 Africa Union members States. The Agenda has seven Aspirations and 20 goals. In Addition, Africa Union has the Science Technology and Innovation Strategy for Africa (STISA-2024) which is the first of the ten-year incremental phasing strategies to respond to the demand for science, technology, and innovation to impact across critical sectors such as agriculture, energy, environment, health, infrastructure development, mining, security, and water among others. Prior to Agenda 2063, in 2007 AU members Countries recognized the potential of science in this case biotechnology and published a policy guideline entitled "Freedom to Innovate" to help Africa countries safety harness biotechnology across several sector-Agriculture (animals and crops), Health and Environment, Industry to spur socio-economic development. To address and ensure that African nations safety applied biotechnology, the Africa Biosafety Network of Expertise (ABNE) was established as biosafety resource network for policy makers and regulators.

Genesis of Biosafety. However, Biosafety in Africa predates from UN Environment-GEF Project on Development of National Biosafety Frameworks started in June 2001 and 2005 for the Program for Biosafety Systems was established targeting specific countries. The advent of ABNE in 2008 has greatly enhanced these efforts and today AUDA-NEPAD-ABNE is on ground in 23 Africa AU Members countries. The current focus for the last decade ABNE and partners has been to build functional biosafety regulatory systems which goes beyond structural frameworks but also enhanced capacity of Africa Union members states to make determinations and sovereign decisions on commercialization of GM crops for socio-economic developments in accord with Agenda 2063 Aspirations and Goals. On international engagements of the Arican Union regarding the implementation of the Convention on Biological Diversity and its protocols mainly the one on biosafety, ABNE, together with AU Commission, serve as secretariat to the African group of negotiators at the Conference/Meeting of Parties. ABNE has also grown from a program to be the Africa Union Development Agency-NEPAD- Centre for Rural Resources and Food Systems and is on ground in 23 Africa Union members states.

Partnerships. It cannot be overemphasized that a decade of excellence requires strong partnership among key stakeholders that have included Africa Union State Governments especially the National Biosafety Authorities such as Kenya National Biosafety Authority hosting this conference, Programs for Biosafety Systems, Africa Agricultural Technology Foundation AATF), National Agricultural Research Institutes among others. Other key partners have included Open Forum for Agricultural Biotechnology (OFAB), Africa Seed Trade Association (STAK) who have played the role for communication and advocacy.

Biosafety Achievements. Today twelve Africa Union Members States have Biosafety Acts and are conducting research at confined field trials (CFT), ten countries have Biosafety Acts with no CFT, 37 countries have no Biosafety Acts and no CFT experimentation and one with CFT using Guidelines. In addition, seven African countries have commercialized biotechnology products including South Africa, Nigeria, Ethiopia, Kenya, Malawi, eSwatini, Sudan. The number crops are gradually increasing and currents commercial release of improved corn, cassava, cotton and cowpeas. Africa is also diversifying into stacked traits and will in the near future make decisions on commercial release of genome edited products.

Apart from crops, AUDA-NEPAD provides support AU member states (Burkina Faso and Mali) undertaking research using gene drives technology to develop genetically modified mosquitoes.

Sustainability of Excellence. After product commercialization the biosafety role becomes limited to monitoring and aspect of product stewardship and so this calls for the need for enhanced commodity-based value chain approach participation of diverse partners in order to sustainable development. This call for involvement of National Governments playing facilitative role, the private Sector, the Farmers and famers cooperatives, financial institutions, development partners among other to spur economic development. Sustainability of the realized gains is very critical through good product stewardship, enhanced seeds systems and strengthening the value chain of each commodity.

New and Emerging Technologies. Twenty-three years after the first commercialization of GM crops, several emerging technologies including genome editing, gene drive and synthetic biology have emerged. As Africa nations need to embrace safe use of these new technologies for socio-economic development and it is noteworthy that safe application will build on the experiences and achievements of the current biosafety frameworks. Furthermore, Africa Nations need support to enhance their capability in policy formulation at the National and Regional levels. ABNE and other partners provide such support to about 35 AU members States. Ongoing support is needed in the Post 2020 Biodiversity Frameworks, current discussion on regulation of Synthetic Biology and need to develop risk assessment guidelines for regulation of gene drives among others.

Gaps. Africa's Freedom to Operate Policy document projected biotechnology applications across several sectors but the status today indicates the need to enhance the current efforts in application in health, animal science, environment and industry which seem to lag behind crops. The lessons we learnt from the COVID-19 epidemic is that Africa needs to building its own capacity in Science Technology and Innovation across all sectors and be able to provide its own solutions to pressing need such as production of COVID vaccines.

The Biosafety Regulatory Framework in Kenya

Dr. Roy Mugiira
National Biosafety Authority

Abstract

Kenya signed the Cartagena Protocol on Biosafety in 2000 ratified it in 2003. The Protocol is the global instrument negotiated under the Convention on Biological Diversity (CBD) as a framework to govern the development, handling and transfer of Living Modified Organisms (LMOs) also referred to as Genetically Modified Organisms (GMOs). Following the ratification of the Protocol, Kenya embarked on the development of the National Biotechnology Development Policy that was published in 2006. In 2009, Kenya enacted the Biosafety Act, the legal framework to regulate activities in genetically modified organisms, to establish the National Biosafety Authority (NBA) and for connected purposes. The NBA is Kenya's national competent authority for the implementation of the Protocol established is to exercise general supervision and control over the transfer, handling and use of GMOs, with a view to ensuring safety of human and animal health, and provision of an adequate level of protection of the environment. In executing its mandate, the NBA works in close consultation with relevant regulatory agencies specified in the First Schedule of the Act. To facilitate the smooth implementation of the provisions of the Act, the NBA published four regulations in 2011.

Key words: Kenya, Biosafety, Regulatory, Framework

Funding biotechnology research in Kenya, Challenges and opportunities

Jemimah Gesare Onsare, PhD
National Research Fund

Abstract

Biotechnology may be broadly classified to fields of Health, Agriculture and Industries. Kenya is moving fast up the biotechnology ladder particularly in agricultural sector in use of tissue culture (TC) technology in production of planting materials; Marker assisted selection (MAS) technology for characterization and mapping of crop pests and diseases, development of drought tolerant crops as well as breeding for desirable traits in crops and animals. Execution of these research activities is done by Government agencies and public/private Research and Development institutions, with financial support from regional and international bodies and some slight support from the Government. Currently, the global trend in Biotechnology health research focuses on molecular and preventive medicine and the use of recombinant DNA (rDNA) and monoclonal technologies. Though there's limited documented biotechnology health research in Kenya, the existing infrastructure, capacity needed for research and the policy instruments raises the prospects of growth in this field. The public Medical Research organization and institutions of higher learning have made some deliberate efforts to initiate biotechnology studies in various health aspects. Funding of expensive research that has highly risky returns can be a major drawback in the Biotechnology field. Continued and enhanced concerted efforts by the Government and other stakeholders in addressing insufficient financial, human resources and infrastructure challenges would sustain biotechnology research in the country. Conversely, realization of the full potential of these technologies will depend on a variety of factors such as embracement of technological change, investment in infrastructure, policy reviews as well as striking a balance on the technology drift between the developed and developing countries which can be addressed through collaborative research. In the wake of a revolutionary world, it's critical as a country to enhance the skills of experts on latest advances in life and allied sciences to remain relevant in biotechnology for a sustainable future.

Key Words: Biotechnology Research in Kenya; Tissues culture technology; Maker assisted selection Biotechnology policy; Government and Donor Funding

Role of KENIA in technology innovations and dissemination

Dr. Tommy Omwansa
Kenya National Innovation Agency

Abstract

KeNIA was established as a Semi Autonomous Government Agency to develop and manage the national innovation system. To achieve these, the agency has six priority to focus on in the shor term, namely; Capacity Development, Commercialization, Policies & Legal Framework, Partnerships & Linkages, Funding and Dissemination & Awareness. To operationalize these priorities, the agency, working with several partners, is currently working on the following products:

1. National Innovation policy (to enable coordination of innovation efforts across the country in all sectors)
2. Commercialization guidelines (to support Universities, TVETs and Research Centers in their commercialization efforts)
3. National Innovation Bridge (a digital marketplace for innovations)
4. Coordination framework for incubation and innovation hubs (to ensure the agency is effectively able to support the establishment and growth of incubation hubs in the country)
5. The national innovation index (a report on the innovation system)
6. Kenya Innovation Week (a platform to disseminate and energize the innovation system on an annual basis)

To develop and coordinate a national system requires that the individual elements of the system work optimally and interact efficiently. These require capacity enhancement, data collection and sharing, effective policies and partnerships; elements that KeNIA is closely working on.

Key words: Innovation, Commercialization, Technology Transfer

Interface between Event Approval and Crop Variety Release and Registration-current Africa's experience, projections on future approvals of stacked traits and decisions on genome edited products

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Abstract

In African countries with Seed Laws all crops varieties registered and commercialized must be approved by relevant agencies under the Seed Act. The approval entails determination of the variety's "value for cultivation", distinctness, stability and uniformity conducted under National performance Trials. However, biotechnology decisions on approval of "GM Events" is based on foods and environmental biosafety regulatory packages. Today several African countries have experiences in biosafety approval of single trait events and variety registration and commercialization. African countries are just embarking on making decisions on stacked traits events and in future will be make determinations on genome edited products for commercial release.

Recently, Nigeria approved stacked traits of drought tolerance and insect resistant other countries such as Kenya, Ethiopia will make decisions on stacked traits events in the near future. Approval of stacked traits require biosafety clearance by the National Biosafety Authorities followed by variety registrations and commercial approval under the Seed laws of specific African countries. Similarly, Africa is conducting research in genome editing in several crops and is currently testing genome edited broad-spectrum rice resistant to bacterial blight. From scientific perspective genome-edited crops may fall under one of the three scenarios- where the final product is equivalent to conventional breed crops, where the final product is equivalent to GM, or where the final product is equivalent to conventional product but had an GM equivalent intermediate which is segregated out called null-segregants.

In backdrop of the preceding scenario, for effective and efficient commercial release of genetically modified with stacked traits and genome edited crops, while ensuring food and environmental safety, there is needed for close collaborations and interplay between the Biosafety Regulatory agencies and the conventional variety release agencies. This paper outlines current experiences in approval, registration, and commercial release of single event traits in Kenya, Malawi, Ethiopia, Nigeria and eSwatini, and projects on future options for approval of stacked events and genome edited crops.

Kenya GM crops variety release and seed certification schemes

Prof. Theophilus Mutui
Kenya Plant Health Inspectorate Service

Abstract

Kenya Plant Health Inspectorate Service is a state corporation in the Ministry of Agriculture, Livestock, Fisheries and Cooperatives (MOALF&C) mandated to offer regulatory services in the agricultural sector. KEPHIS implements the Seeds and Plant Varieties Act (CAP 326) whose major activities are seed certification and Plant Variety Protection. KEPHIS is the liaison office for international conventions Union for the Protection of Varieties and International Seed testing Association.

Genetically Modified (GM) seeds and plant varieties undergo the regulatory requirements stipulated in the Seeds and Plant Varieties Act; a similar procedure through which other conventional crops are undertaken.

The presentation entails the description of the processes that KEPHIS as a regulator undertakes leading to variety release and seed certification. These include Distinctness, Uniformity and Stability (DUS) tests; National Performance Trials (NPT) and Seed Certification. Four varieties of GM Cotton have been officially released for commercialization, while three varieties of Bt Maize have been recommended for release. Approval to conduct NPT for GM Cassava varieties has been granted. Additionally, KEPHIS has facilitated importation of certified GM Cotton seeds for use in Demos on farmers' fields.

Additional information specific to GM crops has been enumerated in the presentation.

Key words: Seed, Variety, Certification, Release.

Role of DVS in management and control of animal diseases

Dr. Obadiah Njagi
Directorate of veterinary Services (DVS)

Abstract

The Directorate of Veterinary Services in Kenya is charged with animal protection and control of animal diseases and pests to safeguard human health, improved animal welfare, increased livestock productivity through production of high quality livestock and their products. It's responsible for developing policies, legislation and regulations relevant to food safety therefore ensuring the safety of food of animal origin.

In this aspect the Directorate deals with live animals and the food chain of animal products. Veterinarians and veterinary paraprofessionals who are the key players in the Directorate are trained in both animal health and veterinary public health (including food borne zoonoses and meat hygiene).

On farm level these professionals ensure that animals are healthy and kept under good sanitary and hygienic conditions. In the control of animal diseases, they play an important role in surveillance, early detection and treatment of diseases in animals.

In the National Biosafety Authority, the Directorate of Veterinary services is one of the key collaborating agencies that perform regulatory roles in regard to relevant genetically modified organisms (GMOs) as specified in Biosafety Act 2009. Together with other regulatory agencies it's involved in the decision making process in safe development, handling and transfer of GMO's. In the livestock Industry some of these GMOs are used in making animal feeds and therefore monitoring safety in human, animals and environment is very important.

Key words: Directorate of Veterinary Services, National Biosafety Authority, Animal diseases, Food Safety

Global regulatory approaches in Genome editing: Special focus on African Countries

John Komen; Matthew Dore; Boniface Mkoko; Doris Wangari Ndegwa
Program for Biosafety systems, Africa

Abstract

Genome editing opens up opportunities for the precise and rapid alteration of crops to boost yields, protect against pests and diseases and enhance nutrient content. As the first generation of genome-edited products have reached commercial release - and considering an expanding R&D pipeline in Africa of projects involving genome editing applications - it comes as no surprise that this expansion of the plant breeders' toolbox gained global attention recently. In contrast to "traditional" genetic modification, genome editing makes use of site-directed nucleases to create breaks at specific, pre-determined points in the host genome. In this way, genes can be tweaked to function better or can be completely switched off.

While the technology is advancing rapidly, the regulatory landscape for genome editing is still evolving and with key countries heading in different directions, this results in a complex geographical pattern of different regulations. Ultimately, the adoption of these techniques is not guaranteed at the scientific level alone: political influences and social acceptance significantly contribute to how crops will perform in the market.

In Africa, several regulatory bodies and stakeholders have assessed the current state of technological progress and evolving global regulatory landscape vis-à-vis their national regulatory frameworks for biotechnology. Based on their analysis, they have developed regulatory approaches to genome editing that are aligned with national biosafety legislation and emerging international best practices. Case studies from Nigeria, Kenya and Malawi will be shared to illustrate this point, and to support policy recommendations.

Key words: Policy; regulation; genome editing; biosafety.

Synthetic Biology - new tools and technologies for accelerating biotechnology

Professor Paul Freemont FRSB FRSC (EMBO member)
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Abstract

Synthetic biology is a rapidly developing interdisciplinary field that is primarily built upon foundational advances in molecular biology combined with engineering design. The field considers living systems as programmable at the genetic level and has been defined by the development of new platform technologies, automation and data-driven design. This has spurned a rapid growth in both academic activities and start-up companies and a new global synthetic biology industry is growing rapidly. In this talk I will discuss the foundations of synthetic biology as a platform technology and provide exemplars of relevant applications. I will also discuss the rapid growth of public-funded biofoundries around the world as a key facilities to enable and accelerate both academic and industrial research.

Introduction to gene drives and its applications in management of malaria in Africa

Mr. Kibet Willy and Dr. Tonui Willy
Bio-consortium Africa Ltd

Abstract

Gene drive is a genetic phenomenon that induces biased inheritance of a specific trait from parent to offspring at an increased chance to upwards of 99% contrary to the 50% Mendelian inheritance. As a result, the selected trait can become common within a particular species over the course of several generations. There are many possible applications of gene drive across public health, agriculture, and conservation. Gene drives rely on the gene editing tool CRISPR/Cas9 system to alter a specific gene and insert a desired gene. For example, disease vectors such as mosquitoes can be altered and prevent them from acquiring and spreading diseases. In malaria control, gene drives can take two forms namely population suppression or population alteration. The principle of population suppression is to knock out the female fertility genes to prevent them from laying eggs or distort sex chromosome inheritance. Population alteration entails a reduction of the vector's ability to transmit disease by preventing the malaria parasite from binding to the receptors within the vector. Currently, different laboratories are conducting gene drive research with potential field applications in Africa to support malaria control and elimination. Stakeholder engagement is crucial during decision making taking into account also the risks and benefits of gene drives. Capacity strengthening of institutions and knowledge sharing will lead to informed decisions on gene drive as well as other emerging biotechnologies. The African Genetic Biocontrol Consortium provides a platform for informational opportunities and in-depth discussion on the needs and requirements for testing genetic biocontrol technologies by experts from African countries that would potentially experience its risks and benefits.

Key words: gene drive, genetic biocontrol

Industry Experiences on Gene Edited Crops

Maria Fedorova
Corteva Agriscience, USA

Abstract

Application of gene editing technology for crop improvement can become an important contributor to reaching global sustainability goals. The talk will provide a high-level overview of the directions in gene-edited product development, industry considerations about appropriate regulatory oversight, and ideas to facilitate the social license of gene editing in agriculture.

Key words: CRISPR, gene editing, technology, policy, social license

Best Approaches to science communication of new and emerging biotechnologies

Dr. Margaret Karembu, PhD, MBS
International Service for the Acquisition of Agri-biotech Applications

Abstract

New and emerging biotechnologies are among the key tools that Africa will rely on to boost agricultural production, achieve food security and nutrition to match the rising demand for food. However, deploying these technologies will rely heavily on development and implementation of policies that foster an enabling environment for research, development, and adoption. Importantly, communication will either hamper or facilitate uptake of these technologies. There is an urgent need to foster open and transparent dialogue with all stakeholders, including those with divergent views on these technologies, in order to build consensus and common understanding. To achieve this, effective communication is paramount. In the advent of new breeding innovations, including CRISPR genome editing, pertinent questions arise. Is Africa going to be a follower or can it become a leader in tapping into associated benefits of these technologies? What lessons from crop biotechnology could help build trust in delivering these technologies to farmers who need them most? This presentation will explore lessons from 25 years of commercial cultivation of biotech crops, and best practices in communicating about new and emerging biotechnologies. A special focus will be given to the role of the newly formed African Coalition for Communicating about Genome Editing that seek to foster constructive dialogue amongst stakeholders.

Key words: Science communication, new and emerging biotechnologies, dialogue, trust

Registration and roles of institutional Biosafety Committee (IBC)

Ngetich Nehemiah
National Biosafety Authority

Abstract

IBC guidelines provides guidance to organisations that have Institutional Biosafety Committees (IBCs) or intend to set up an IBC in compliance with the Biosafety Act, 2009 and the Biosafety (Contained Use regulations) 2011. As a statutory committee that operates from the premises of an organisation, the IBC is in a position to conduct onsite evaluation, assessment and monitoring of adherence to the biosafety guidelines with overall oversight of the regulatory process, at the institutional level. The decisions taken by the National Biosafety Authority (NBA) are based on the applications submitted by the investigators through the IBC. Therefore, it is pertinent that IBCs have expertise in evaluation, assessment and monitoring of projects and ensure compliance with the Biosafety Act, 2009, the Biosafety (Contained Use regulations) 2011 and other guidelines issued by NBA from time to time. These guidelines describe the composition and roles of IBCs. The guidelines provide information for compliance requirements by IBCs and processes to be followed while dealing with living modified organisms or recombinant DNA materials (LMO/rDNA) in line with the Biosafety Act, 2009

Key words: IBC, Contain use regulations, GMO

Potential Role of Bt Maize in The Realization of Food and Nutrition Security in Kenya

James Karanja, S Mugo, Y Beyene, A Too, M Mwimali, R Tende, F Maritim, S Oikeh and E Kireger
Kenya Agricultural and Livestock Research Organization (KALRO)

Abstract

Biotech crops addressing different production constraints are the most widely adopted agricultural technologies globally of which maize occupies 31% by 2019. Genetically engineered (GE) maize producing insecticidal proteins from Bacillus thuringiensis (Bt) (mainly Cry proteins) has been used to effectively control different species of stem borers, fall armyworm (FAW), and other Lepidopteran pests worldwide. In Kenya, there are over 150 Bt Bio-products registered and accessible by the smallholder farmers with different Bt strains. Kenya in partnership with AATF, Bayer, CIMMYT and National Agricultural Research Systems of South Africa, Mozambique, Tanzania, Uganda, Nigeria, and Ethiopia under the TELA Maize Project developed and tested MON810 (Bt) maize varieties in confined field trials sites at Kitale and Kiboko and six national performance trial sites. The trials were artificially infested with stem borers, without protection against fall armyworm. The evaluations showed the potential of Bt maize in management of stem borer and FAW with mean leaf damage scores of <2.4 in Bt varieties against >5 in the non-Bt and commercial varieties on a scale of 1-9. The Bt maize varieties gave the highest grain yield of > 6.5 ton/ha compared to non-Bt and commercial varieties with < 4 ton/ha. Similar results have been reported in the partner countries with some recording over 80% yield advantage against the mean of commercial checks depending on the level of infestation by the target pests. Bt maize therefore, when commercialized, has great potential to enhance maize productivity from 1.8ton/ha to 3to 4ton/ha and thus, increased farm income, reduced the annual 4 to 6 million bags (90kg bag) maize imports occasioned by the shortage, reduced use of insecticides and protect human health and environment, improved quality of maize grains due to the reduction in rotten grains from insect damage and the occurrence of ear molds and lowering levels of carcinogenic aflatoxins produced by molds.

Key words: Fall armyworm, Grain yield, Insect-pest protected, Stem borer, TELA maize

Genome edited Banana for Disease Resistance- Status Update

Dr. Leena Tripathi, Valentine Ntui, Jaindra Nath Tripathi
International Institute of Tropical Agriculture (IITA)

Abstract

Banana (Musa spp.) is one of the major staple food crops grown in over 136 countries in the subtropics and tropics with annual global production of around 153 million metrics, feeding about 500 million people. Its production is constrained mainly by diseases and pests. The use of disease-resistant banana varieties is one of the most effective options to mitigate the negative impacts of pathogens in banana production. CRISPR/Cas9 based genome editing has emerged as the most powerful tool for crop improvement due to its capability of creating precise alterations in plant genome and trait stacking through multiplexing. Recently, the robust CRISPR/Cas9-based genome editing of banana has been established, which can be applied for developing disease-resistant varieties. The CRISPR/Cas9-based editing was applied to inactivate the integrated endogenous banana streak virus (eBSV), dsDNA badnavirus, integrated into the B genome of plantain (AAB), overcoming a major challenge in breeding and the dissemination of hybrids. The gene-edited events of plantain 'Gonja Manjaya' were generated with mutations in the targeted sites of integrated eBSV sequences in the host genome. Sequencing and phenotyping of the edited events showed targeted mutations and confirmed the inactivation of eBSV for its ability to be converted into infectious viral particles.

IITA is currently advancing the application of gene-editing to control the banana Xanthomonas wilt, the most destructive banana disease in East Africa. BXW disease can be controlled by disrupting the function of disease-causing susceptibility ('S') genes, nutrient transporters, or negative regulators of plant defense. Recently, we demonstrated that disruption of the banana orthologue of the downy mildew resistance 6 (MusaDMR6) gene showed enhanced resistance to BXW disease. A synopsis of recent advancements in the application of gene-editing of banana will be presented during this conference.

Key words: Banana, Bacterial wilt disease, Banana Streak Virus, Gene Editing

Biotech potato with complete resistance to late blight disease

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Abstract

Potato, the 3rd world food crop, is an increasingly important crop that provides both food and cash income. In Kenya, potato is the second most important food and cash crop mainly grown by small-scale farmers with a national production of 2 Mt with an average yield of 9.4 t/ha. It provides nutritional benefits such as vitamin C and provides employment for more than 2.5 million people. Yields still stagnate below 10 t/ha due to a combination of inadequate supplies of high-quality seed, pests and diseases and limited awareness of better crop management practices. Late blight (LB) disease is prominent and is responsible on average for 15% yield loss in Kenya. The disease is controlled almost exclusively by applying from 3 to 15 sprays of fungicides per season which affect farmers health and the environment. Potato breeders have released varieties with variable levels of LB resistance which still need fungicide sprays and often loosing resistance after few years. We have transferred 3 resistance genes from wild relatives of the potato (RB, Rpi-blb2 from Solanum bulbocastanum, Rpi-vnt1.1 from S. venturii) into five existing farmer and consumer preferred varieties (3R potato) with four of them been grown in Kenya. Transgenic events were tested in the lab, greenhouse and in the field. More than a dozen field trials, some in three locations, for over six years in Uganda demonstrated complete resistance to LB. The stack of 3 resistance gene ensures the resistance to late blight to be more durable than single resistance gene. Molecular characterization identified a clean insertion event and its field performance revealed it is a good candidate for future release to farmers. These results and their potential to solve one of the most important plant diseases will be presented.

Key words: Potato, genetic engineering, late blight disease, Kenya

GM Crops and their Contribution to the EU Feed Sector

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CropLife, Europe

Abstract

Genetically modified (GM) crops are essential to the European Union feed sector. The EU is 70% import-dependent on high-protein feed sources. According to the European Feed Manufacturers' Federation, soybean, maize, and rapeseed are among the most important crops used as feed for livestock in the EU. In fact, soybean meal contributes 28% of the total livestock feed in the region positioning soybean as the leading crop in provision of this feed. Interestingly, the EU only produces about 3% of her soybean needs while the 97% deficit is met by imports which are GM. EU soybean meal imports largely come from Brazil and Argentina, where GM adoption rate is at over 90%. Notably, EU's authorization system for cultivation dossiers of biotech crops is dysfunctional with only one authorization of insect-resistant maize made in 1998.

Key words: Genetically modified, soyabean, livestock feed.

Progress and roadmap towards commercialization of disease resistant GM cassava in Kenya

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Abstract

Cassava is widely grown in Kenya as a staple food and source of income, mainly by smallholder farmers. Its production is constrained, however, by two viral diseases; cassava mosaic disease (CMD) and cassava brown streak disease (CBSD). The Virus Resistant Cassava for Africa (VIRCA Plus) project applied modern biotechnology to produce GM cassava with robust resistance to CBSD. This was achieved through genetic engineering of farmer preferred cassava variety TME 204, and selection of the lead Event 4046 across multiyear, multilocational, regulated field trials in Kenya and Uganda. Studies showed no significant changes in food, feed and environmental characteristics between the improved cassava and conventional TME 204. Data was compiled and a regulatory application submitted by the Kenya Agricultural and Livestock Research Organization (KALRO) to the National Biosafety Authority (NBA) for environmental release and placing on the market of cassava Event 4046. In parallel, KALRO scientists performed a breeding program under regulated field conditions to develop varieties best suited to Kenyan farmers in which Event 4046 was crossed with the farmer-preferred CMD-resistant cultivars TME 14 and NASE 14. A population of the resulting F1 progeny were evaluated under high CMD and CBSD disease pressure. Best performing lines were advanced to Yield Selection Trials (YST) conducted over successive cropping cycles at Coast (Mtwapa), Western (Alupe), and Central (Kandara) regions of Kenya. After review of the regulatory application with the required public participation, approval was granted by the NBA to perform National Performance Trials (NPTs) of progeny lines derived from Event 4046. Eight lines which have demonstrated very high levels of CBSD and CMD resistance plus high yields and good agronomic characteristics have been selected for advancement to NPTs at three Coast, three Western and one Central location. A distinctiveness, uniformity and stability (DUS) trial will also be conducted under the supervision of Kenya Plant Health Inspectorate Service (KEPHIS) during 2022-2023. The best performing lines will be submitted to national variety release committee for commercial release. The project has conducted all its research and trials in compliance with NBA regulations, guidelines and supervision.

Key words: GM Cassava, Disease resistance, Modern biotechnology

Biography of Dr Jeremy Tinga OUEDRAOGO

Head/Coordinator AUDA-NEPAD Africa Biosafety Network of Expertise and Integrated Vector Management programmes
Head of AUDA-NEPAD Centre for Rural Resources and Food Systems.

Dr. OUEDRAOGO is a scientist in genetics and plant breeding and got his PhD in Canada. He focused his research on the use of biotechnology and biosafety tools in crops. As a plant breeder, he has established the Plant Genetics and Biotechnology laboratory in the national research system of Burkina Faso. He has contributed to create many cowpea varieties that are released in Burkina Faso as well as in West African countries.

From 2007 to 2014 he has been elected Member of Parliament and nominated Minister of Animal Resources and Fisheries in Burkina Faso.

Dr Ouedraogo is also a member of the Board of Trustees of the African Agriculture Technology Foundation (AATF) that is based in Nairobi, Kenya.

NOTES

NATIONAL BIOSAFETY AUTHORITY

Championing for a Biosafe Nation

VISION STATEMENT

A World-class Biosafety Agency.

MISSION STATEMENT

To ensure and assure safe development, transfer, handling and use of genetically modified organisms (GMOs) in Kenya.

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