

# **Biosafety News**

Championing for a Biosafe Nation NBA is ISO 9001:2015 Certified

Issue No. 6



### **Celebrating a Decade of Biosafety Regulatory Excellence**

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- NBA Conducts Capacity Building for the Institutional Biosafety Committee

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Biosafety Kenya



@BiosafetyKenya

## **EDITOR'S NOTE**

Dear readers,

appy New year to you all!

Welcome to the 6th Issue of the Biosafety News, our bi-annual newsletter from the National Biosafety Authority. The National Biosafety Authority (NBA) has strategically positioned itself in its operational environment by aligning itself effectively to biotechnology changes. This is evident in some of the activities in the past two quarters, and successes realized that placed the Authority in the limelight.

The Authority successfully conducted the Annual Conference under the theme: "A Decade of Biosafety Regulatory Excellence: Experiences and Lessons". The Conference was officially opened by the Cabinet Secretary, Ministry of Education, Prof George Magoha. The forum presented an opportune time for the celebration of a decade of excellence in Kenya's biosafety Regulation.

Regarding capacity development, we hosted a successful briefing Session for the Chief Executive Officers of Biosafety Regulatory Agencies. We also held a forum for capacity building of the Institutional Biosafety Committee (IBC) members. In addition, the Authority conducted a Stakeholder Validation Workshop for Adventitious Presence (A.P.) and Low-Level Presence (LLP) Guidelines.

We have many thought-provoking articles that will make you discover more about the strides made in our journey towards ensuring that the country has a functional Biosafety regulatory framework as envisaged in the Biosafety Act.

Enjoy the read!

**Brian Abook** 







Dear Esteemed stakeholder,

Since its establishment in 2010, the National Biosafety Authority (NBA) has strived to deliver on its mandate by ensuring that the country has a functional Biosafety regulatory framework as envisaged in the Act. Some of the objectives are:

- 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

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. That being the case, our role as a regulator is cut out. As you are aware, 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.

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 G.M. cassava is in the final phase of being availed to the farmers for cultivation.

For the past two quarters, our key focus was on approval for the environmental release of the G.M. Cassava. Cassava is one of the significant sources of farm income and is an important food security crop for the people of Africa. Moreover, being the third African staple food crop after maize and rice, it remains an essential diet for millions of Africans.

The genetically modified (G.M.) cassava is an improved cassava variety resistant to Cassava Brown Streak Disease (CBSD). Cassava brown streak disease (CBSD) is a viral disease of cassava that poses a significant threat to food security, with infections rendering plants inedible for both humans and animals and can wipe out the infected crops in an entire farm.

The technology used in the modified cassava has been used globally in other already commercialized crops such as papaya, squash and plums consumed by humans in China and the USA without any known negative human or animal health implications.

As a result, 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 as well as manufacturing at the value chain addition.

## Prof. Dorington Ogoyi *CEO, NBA*



## **Announcing a New Board Member**

The National Biosafety Authority (NBA) is pleased to announce a new board member. Her profile is indicated below:



Ms Caroline Mweni,
Representative of the National Treasury

Ms Caroline Mweni is an Economist with over 11 years of experience in Economic Policy and Public Finance Management. She holds a Bachelor of Science degree in Economics and Mathematics from Kabarak University and a Master of Arts Degree in Economics and Policy Management from the University of Nairobi. She is also a zmember of the Economist Society of Kenya.

She has been engaged in resource mobilization and negotiations for externally financed programmes and projects with Multilateral and Bilateral Agencies on behalf of the Government of Kenya. Further, Mweni has robust experience in donor harmonization and coordination, and she has actively drafted various policy papers on Public Finance Management

#### **Enhancing Our Human Resource Capacity**

In a bid to enhance the human resource capacity, the National Biosafety Authority (NBA) hired new employees to fill key staff positions previously vacant. Their profiles are highlighted below:

#### 1. Director, Technical Services (DTS)



Dr Roy B. Mugiira joined the National Biosafety Authority (NBA) in August 2021 as the Director, Technical Services (DTS). He holds a PhD in the diagnosis of plant viral infections based on the alignment of their DNA sequences. He has research experience in the cloning of viral DNA genomes into gene silencing vectors for application in functional genomics Dr Mugiira played a key role in developing Kenya's Biotechnology Development Policy and the Biosafety regulatory framework for Genetically Modified Organisms. He is a member of the Biosafety Risk Assessment Panel of Experts for the Cartagena Protocol on Biosafety and served as the Acting Chief Executive Officer of the NBA at its formative stages.

He has a wide experience in policy advisory for the governance of Science, Technology and Innovation (ST&I) generally and Biotechnology Development specifically. Previously, he served as the Director of Research, Ministry of Education – Kenya and Director, Scheduled Sciences at the National Commission for Science, Technology and Innovation (NACOSTI).



# 2. Director Finance and Administration (DFA)



Ms Ann N. Karimi joined the National Biosafety Authority (NBA) in October 2021 as the Director, Corporate Services (DCS). She is a qualified Financial Analyst with over fifteen years of experience in Pensions, Investments, Finance, Administration and the Asset Management Industry across various sectors.

Ms Karimi is currently pursuing a Doctor of Philosophy in Business Administration with a Major in Finance. In addition, she holds a Master of Science in Finance Degree from the University of Nairobi and a Bachelor of Science Degree in International Business Administration (IBA) with a Major in Finance from United States International University (USIU).

She is a Full Member of the Institute of Certified Financial Analysts (ICIFA) and the Chartered Institute for Securities and Investments (CISI).

Before joining National Biosafety Authority (NBA), she held various senior positions in both the public and private sector, including; Financial Analyst, Head of Credit, East Africa, Head of Pensions and Institutional Business, and held Directorships in the private sector. In addition, she is a Finance and Leadership enthusiast with a certification in Strategic Management and Leadership from the Kenya Institute of Management.

#### 3. Corporation Secretary

CS. Moses Lukale Sande is an advocate of the High Court of Kenya of over Ten (10) years standing and a Certified Secretary of Kenya (CSK). He holds a Bachelor of Laws degree (LL. B) from the University of Nairobi, a post-gradu-



ate Diploma in Law from the Kenya School of Law, and a Master of Laws degree (LL.M) in International Criminal Justice and Armed Conflict from the University of Nottingham, United Kingdom. Furthermore, he successfully completed the Senior Management Course from the Kenya School of Government.

C.S. Sande has vast experience in corporate governance, Devolution, International Criminal Justice, Human Rights, Peace Support Operations, and Disaster Management. Before joining NBA, he held various positions in the public and private sectors, his last appointment being Corporation Secretary and Legal Manager at the Kenya National Trading Corporation

#### **4. Senior Planning Officer**



As the Senior Planning Officer, Ms Hellen G. Karuiru joined the National Biosafety Authority (NBA) in July 2021. She is an Economist and finance professional with over eight years of experience in strategy, planning, project management, and Finance spanning from the private and public sectors.

Ms Hellen holds a Master of Science in Finance Degree and a Bachelor of Economics and Statistics Degree from the University of Nairobi. Also, she is a Certified Public Accountant (Part 1) and a full member of the Institute of Economic Affairs Kenya.



#### 5. Biosafety Officers



Ms Fridah Kagendo Kiunga is an expert in plant breeding and biotechnology with a vast experience of over ten years. She holds a Bachelor of Science in Agricultural Biotechnology from Moi University and a Master of Science Degree in Plant Breeding and Biotechnology from the University of Eldoret.

Before joining NBA, she worked in various public sectors, including KEPHIS, TVET-CDACC, UoE and Kalro, in plant breeding and biotechnology applications.



Mr Alinda Alfred is a Biosafety Officer at the National Biosafety Authority. His academic background includes a Master's of Science in Molecular Biology with a prior undergraduate degree in Biotechnology.

#### **6. Records Management Officer**



Mr Humphrey Wandaka Kimani, is a Records Management Officer at the National Biosafety Authority. He holds a Bachelor's degree in Information studies and a Diploma holder in Library and information studies.

Mr Wandaka has nine years' experience in the field of records management and one-year experience in Library science.

#### 7. Office Assistant



Ms Regina Kibor is an Office Assistant at the National Biosafety Authority. She holds a Diploma in Supply Chain Management and aspires to grow within the Authority

#### 8. Driver



Mr Nicholas Peter Kasyoki is a driver at the National Biosafety Authority. He has a certificate in Executive Driving, National Youth Service training, First Aid, Defensive Driving and Occupational Trade Test.

Currently, Mr Kasyoki is placed in the Administration Department-Transport section.

## NBA Board Approves Environmental Release Application for G.M. Cassava

he National Biosafety Authority (NBA) Board, during the 41st Full Board Meeting held on 15th June 2021, approved the application for the environmental release of genetically modified (G.M.) cassava. The approval was based on food/feed safety and environmental safety assessment which showed that the cassava varieties containing Event 4046 are unlikely to pose any risk to human and animal health or the environment when consumed as food or feed or cultivated in the open environment. The variety was thus shown to be as safe as the conventional varieties that farmers have cultivated over the years. This approval implies that Kenya is the first country globally to consider a request for environmental release involving cassava crops.

After several years of laboratory, greenhouse, and confined field trials conducted locally in Mtwapa, Alupe, Kandara and Nairobi by Kenyan scientists, the application for environmental release and placing on the market of genetically modified (G.M.) cassava was submitted to the NBA by Kenya Agricultural and Livestock Research Organization (KALRO) on 9th March 2020. The G.M. Cassava has been developed using RNA interference (RNAi) technology. RNAi is a natural biological mechanism that regulates the expression of genes. The improved cassava is resistant to Cassava Brown Streak Disease (CBSD) because of the modern biotechnology used to express high resistance levels. CBSD is a common viral disease in Kenya and is spread by whiteflies and by infected cuttings. Cassava farmers will be protected from devastating losses caused by CBSD. Farmers will benefit from increased cassava root quality and marketable yield with consumers. This technology has been used globally in other already commercialized crops like papaya, squash, and plums consumed by humans in

China and the USA without any known human or animal health implications.

Earlier last year, an announcement was made to invite the public to submit written comments or memoranda within 30 days. The cassava application summary was placed in the dailies (Daily Nation and Standard Newspaper), Kenya Gazette, and NBA website on 15th May 2020 and comments were received until 14th June 2020. A public forum on the application was also held on 10th June 2020. Issues raised during the public participation were adequately addressed.

The G.M. cassava application was reviewed by experts on food safety, environmental safety assessment and the Relevant Regulatory agencies and was shown to be as safe as the conventional cassava variety. For socio-economic impact assessment, analysis and expert opinions indicate that G.M. cassava is not expected to change the farming systems currently in Kenya. On the contrary, the effective management of CBSD disease will be of economic and social benefit to the Kenyan population.

The anticipated increase in cassava yields resulting from the intervention will significantly contribute to addressing Food Security and Nutrition, and Manufacturing. The two are part of the governments' 'Big 4 Agenda', which were launched to end hunger, achieve food security, improve nutrition, and promote sustainable agriculture.

This approval is for the purpose of conducting National Performance Trials (NPTs), which is the penultimate stage for full environmental release and placement into the market. The board will consider full approval after the NPTs have been finalized. This approval is valid for five (5) years from the date of authorization.



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#### **Celebrating a Decade of Biosafety Regulatory Excellence**



A group photo of the Chief Guest, Prof. George Magoha, Cabinet Secretary-Ministry of Education together with the CEO-NBA, NBA Board members and the sponsors of the 10th Annual Biosafety Conference.

he National Biosafety Authority celebrated its 10th Annual Biosafety Conference. With the theme: "A Decade of Biosafety Regulatory Excellence: Experiences and Lessons", the Conference provided a prime forum to celebrate a decade of excellence in Kenya's biosafety regulation.

The Conference was officially opened by the Cabinet Secretary, Ministry of Education, Prof George Magoha, the chief guest. It attracted delegates from all over the world, people with wide-ranging knowledge on biotechnology and biosafety related matters. Participants got the chance to share experiences and collect lessons



to enhance efficiency in the National Biosafety Regulatory Framework.

Unlike last year's virtual Conference, this year NBA held a hybrid conference. The Conference was conducted from 4th – 5th November 2021, opening with a keynote address on the "Evolution of Biosafety Systems in Kenya and Africa", and 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 G.M. cassava in Kenya;

The Conference was preceded by a two-day pre-conference virtual workshop that was held 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 (A.P.) 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; Our special gratitude goes to our key sponsors, namely; CORTEVA, Bayer Crop Science, African Union Development Agency (AUDA-NEPAD), African Agricultural Technology Foundation (AATF) and the Programme for Biosafety Systems (PBS) and National Research Fund (NRF) who are also here with us.

We thank all the participants who created time to be with us at the Conference.



A group photo of the NBA Board, conference sponsors and some of the participants.

#### **Current Approval Status of GMOs in Kenya**

- Ann Muia

The National Biosafety Authority is mandated to regulate GMOs through the entire chain of the development process (Laboratory, Greenhouse and Confined Field Trials) to Environmental release (National Performance Trials and Commercialization). This means that the NBA receives and reviews both Contained-use (Research) and Environmental Release applications. For the research phase, the review process's focus is to ensure that research mate-

rials are contained in the research facilities; that is, entry of research materials into the food chain or release to the environment is prevented. At the stages of environmental release, the focus is on food/ feed safety and environmental safety aspects. The NBA approval process for GMOs at any stage is geared towards ensuring and assuring safe development, transfer, handling and use of genetically modified organisms.

Upon completion of the research process, developers can advance to the environmental release stage. An environmental release application review process involves Food safety assessment (uses data generated according to Codex, OECD guidelines); Environmental risk assessment (uses data generated according to Annex III of Cartagena Protocol on Biosafety). In addition, the socio-Economic assessment

puts into consideration parameters that are relevant to Kenya. The NBA engages experts from all these fields and relevant regulatory agencies to ensure the thoroughness of the review process. Members of the public are usually also invited to give their comments. Some projects that have progressed to Environmental release are as summarized below:

Status	Contained use (Lab / Greenhouse)	Contained use (CFTs)
Approved	36	14
Rejected/ Withdrawn	0	0
Pending	3	1
Total	39	15

Application/Project	Status	
Bt maize	NPTs successfully completed in Embu, Mwea, Kandara, Kibos, Kakamega & Alupe	
Bt Cotton	Commercialized	
Modified colour Gypsophila flower	Rejected	
Virus resistant Cassava	NBA conditional approval (for NPTs) granted in June 2021	

The Authority received from the Kenya Agricultural and Livestock Research Organization (KALRO) an application for environmental release, cultivation and placing on the market of cassava event 4046 and its varietal derivatives in Kenya on 9th March 2020. Before making the environmental release application, KALRO partnered with Donald Danforth Plant Science Center, USA conducted confined field trials (CFT) of virus-resistant cassava in Mtwapa, Kilifi County; Kandara Murang'a County and Alupe, Busia County. In addition, concurrent CFT tests were done in Uganda by the National Crops Resources Research Institute (NaCRRI).

As required under the Biosafety Act No. 2, 2009, when the Authority received the application, an application summary was posted on the NBA website; a public notice was placed in two nationally circulated newspapers and the Kenya Gazette on 15th May 2020. Public comments were received within 30 days up to 14th June 2020. A public forum on the application

was also held on 10th June 2020 through a virtual zoom meeting. From the public participation, 93.7% supported the release of the cassava, 3.9% were opposed, while 2.2% were neutral. The application was sent to regulatory agencies including KEPHIS, NEMA, DVS and the Department of Public Health for comments based on their respective mandates. Independent experts further reviewed the application on food safety, environmental safety and socio-economic impact assessment.

The overall conclusion of the assessment was that: Cassava varieties containing event 4046 are unlikely to pose any altered risk to the environment compared to conventional cassava varieties, and; Food and feed derived from event 4046 cassava are as safe as those derived from conventional cassava varieties.

An approval for environmental release was thus given, on 18th June 2021, for the purpose of conducting National Performance Trials (NPTs) for Event 4046 in cassava varieties in Kenya



GM Cassava crops at the Confined Field Trials in Mtwapa / Photo Courtesy of ISAAA.

#### Biosafety dossier review and evaluation by the NBA in Kenya

- Dr. Billy Omboki Ratemo

The National Biosafety Authority (NBA) is the nation's premier agency mandated to supervise and exercise general control over the development, transfer, handling and use of Genetically Modified Organisms (GMOs). The Authority has developed regulations that govern environmental release; export, import and transit of genetically modified (G.M.) commodities; contained use; and labelling regulations to achieve its mandate. Reviewing and evaluating application dossiers is critical to making decisions that safeguard against GMOs' diverse effects on humans, animals, and the environment.

A biosafety dossier is a piece of information (or data) that a Principal Investigator (P.I) submits to NBA to enable the Authority to decide with regards to the movement of genetically modified material or use of Genetic Engineering (G.E.) techniques on an organism to achieve a desired commercial outcome. NBA reviews the dossier in collaboration with other agencies to ensure adequate safeguards are available.

Some of the agencies NBA collaborates with to review the dossiers include: the National Environment Management Authority (NEMA), Department of Veterinary Services (DVS), Department of Public Health (DPH), and Kenya Plant Health Inspectorate Service (KEPHIS), and Kenya Bureau of Standards (KBS). The involvement of these agencies is dependent on the scope of the project that seeks approval. The dossier contains data that describes the GMO, which includes features of the donor, recipient organisms, the modification and its effects; environmental safety that includes agronomic features, intended and unintended



effects of the recipient organism, impact on the environment (potential for gene flow, effect on pests, invasiveness etc.); and food and feed safety information like compositional, nutritional features, toxicity and allergenicity of the product, effects of processing on the product, change in dietary composition among others.

The regulations ensure that genetically modified products are developed and delivered safely with minimal or no negative impacts on the end-user (people or animals) and the environment. The regulations are science-based, which take into account the end-use of the product and is done in a case-by-case manner. The process is multi-faceted and multi-disciplinary, enhancing the ability to detect unintended effects and involving collaborative efforts of environmental, plant, toxicological,

biochemical, nutritional, and molecular scientists.

The gathered information is then submitted to a diverse panel of experts to give opinions on different dossier sections. Next, the experts develop a decision document detailing the risks associated with approving the project by considering perceived effects on the environment, food and feed, socio-economic, ethical and legal issues. The NBA ensures that the experts do not have any conflict of interest with the application undergoing review. Finally, the document is submitted to the public to submit their views before the NBA makes public its decision on whether to approve, reject the application – with terms and conditions.



Figure-1: Regulatory approval process and evaluation of biosafety dossier.



## Stakeholder Validation Workshop for Adventitious Presence (A.P.) and Low-Level Presence (LLP) Guidelines



A group photo of the NBA members and key stakeholders during the stakeholder validation workshop for LLP and A.P. at the Movenpick Hotel, Nairobi.

On Thursday, 16th September, the National Biosafety held a successful workshop for stakeholder validation of the guidelines managing the Low-Level Presence (LLP) and Adventitious presence (A.P.) situations of Genetically Modified Organisms (GMOs) in Kenya.

'Low-level presence' refers to trace amounts of GMOs in grain or food shipments that have been approved in the country of production but not in the country of import. On the other hand, 'Adventitious Presence' occurs when trace amounts of an agricultural biotech product that has not been approved for commercial use find their way in the commercial crop or food supply despite best agricultural and manufacturing practices.

Worldwide, there is a high rise 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. The

variations affect key trading countries, especially where there is the detection of low-level presence of biotech crops where imports have been made to countries that do not approve the affected product.

Faced with this dilemma, NBA needed to engage stakeholders in developing guidelines that manage the LLP and A.P. in Kenya. The meeting was a follow-up of several initiatives. Earlier in the year, NBA and stakeholders drafted the guidelines and then reviewed them, and the guidelines are now at the stakeholder validation stage. The workshop presented an opportunity for stakeholders to develop a common understanding of LLP & A.P., review the proposed guidelines for regulating LLP & A.P. for further processing and adoption, and align the proposed guidelines with the biosafety labelling regulations and Biosafety Act, especially as it relates to seed-trade.

Kenya has made outstanding achievements in the advancement of biotech crops.



Three leading crops that mark the milestones that NBA has made as a regulator are; Bt Cotton, which has been commercialized, Bt Maize which has already gone through the National Performance Trials (NPTs) and recently, the G.M. Cassava, which was approved for NPTs.

In his opening remarks at the workshop, the NBA CEO, Prof Dorington Ogoyi, welcomed all the stakeholders and reiterated the importance of countries to develop trade-friendly LLP and A.P. policies and at the same time ensure food, feed and environmental safety and public confidence.

The stakeholders present in the validation workshop were from the Program for Biosafety Systems (PBS), Directorate of Veterinary Services (DVS), Ministry of Education, National Environment Management Authority (NEMA), Kenya Plant Health Inspectorate Service (KEPH-IS), Kenya Agricultural and Livestock Research Organization (KALRO), African Agricultural Technology Foundation (AATF), International Service for the Acquisition of Agri-biotech Applications (ISAAA), Corteva Agriscience, Cereal Growers Association, Civil societies and consumer associations. The stakeholder workshop was sponsored by the Program for Biosafety Systems (PBS).

#### **Staff Members Participate in Tree Planting Exercise**

Staff members from NBA participated in a tree planting exercise at the National Commission for Science, Technology and Innovation (NACOSTI) compound. The tree-planting initiative supports the high priority Government-driven initiative conceived in the 2019/2020 financial year to implement the Presidential directive and National Strategy for achieving and maintaining over 10% Tree Cover by 2022.

NBA is committed to ensuring an adequate number of tree seedlings are planted in its corporate social responsibility projects as part of the Government's Panda Miti, Penda Kenya drive that H.E. President Uhuru Kenyatta officially launched. The Authority's tree planting drive is geared to conserve the environment.

According to the government, approximately 1.8 billion tree seedlings must be planted to achieve ten per cent tree cover by 2022.



NBA staff members in a tree planting exercise at NACOSTI.



# Photo Gallery





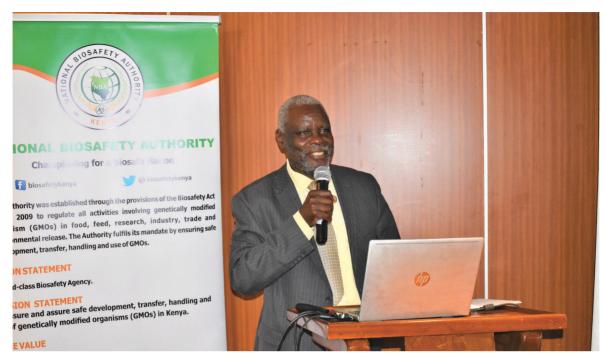






- 1. Dr Joseph Chavutia, Chairperson- NBA Board of Directors, giving a speech during the 10th Annual Biosafety Conference at Sawela Lodges, Naivasha.
- 2. Education Chief Administrative Secretary (CAS) Ms Mumina Bonaya with the NBA CEO and some staff members
- 3. Panel discussions during the 10th Annual Biosafety Conference
- 4. Display of a G.M. cassava by one of the biosafety officers
- 5. Attendees following the proceedings during the 10th Annual Biosafety Conference at Sawela Lodges- Naivasha

# Briefing Session for Chief Executive Officers of Biosafety Regulatory Agencies



NBA CEO making a presentation during the briefing session for Chief Executive Officers of Biosafety Regulatory Agencies.

The National Biosafety Authority (NBA) conducted a briefing session for Chief Executive Officers (CEOs) of Biosafety Regulatory Agencies in Kenya. The objective of the meeting was to appraise CEOs of Regulatory Agencies on the biosafety regulatory framework

and coordination structure. The CEOs were also updated on the status of GMO approvals and biosafety regulatory challenges faced in the approval process.

The meeting was held at Sarova Panafric Hotel, Nairobi.

### Consultative Meeting on Guidelines for Food Safety Assessment, Environmental Risk Assessment, and Stacked G.M. Events

The advancement of biotechnology has significantly contributed to the development of Stacked genetically modified (G.M.) crops. Stacked G.M. crops are a product of Stacked G.M. Events. Stacked G.M. events are the creation of a genetically modified organism (GMO) with more than one genetic modification.

Stacked genetically modified (G.M.) crops are becoming popular for their enhanced production efficiency and improved functional properties. This situation has triggered the need for strengthening the guidelines for the regulation of stacked genes.

The National Biosafety Authority held a consultative meeting on guidelines for food safety assessment, environmental risk assessment,



and stacked G.M. events. The objective of the meeting was to build a consensus among the stakeholders on; (a) a shared understanding of stacked genes, (b) a basic technical understanding of the methodologies applied in understanding stacked genes, and (c) review the

developed draft guidelines for the regulation of stacked genes.

The stakeholders present in the meeting were from regulatory agencies in Kenya, research organizations, universities, the Agriculture Sector Network, the private sector, and other relevant stakeholders.



Presentation by an NBA Biosafety Officer during the Consultative Meeting on Guidelines for Food Safety Assessment, Environmental Risk Assessment, and Stacked G.M. Events.

# NBA Conducts Capacity Building for the Institutional Biosafety Committee

The National Biosafety Authority (NBA) held a forum for capacity building of the Institutional Biosafety Committee (IBC) members on 30th August 2021 at the Movenpick Hotel, Westlands- Nairobi.

The forum provided a platform to interact, recognize and appreciate the critical role that the IBCs play in facilitating biosafety compliance in Kenya. In addition, it offered the IBCs an opportunity to exchange experiences, network, and share expertise to improve their operations.

During the forum, the IBC members were updated on the review process in GMO applications and the stipulated requirements for establishing IBCs as an advisory body in research institutions dealing with GMOs in Kenya. Members were also informed about the new and emerging biotechnologies and were given a chance to propose the best approaches on their risk assessments and regulations.

During the forum's opening session, the NBA CEO, Prof Dorington Ogoyi, welcomed the various IBC members. He further acknowledged and appreciated the support and partnership of



the Program for Biosafety Systems (PBS) towards the forum.

IBCs are a statutory committee that serves as the scientific and administrative arm of the organization on compliance with biosafety law. They comprise Biosafety officer(s); Scientist(s) in the relevant field; Representative(s) of technical staff; Representative(s) of laboratory management; Representative(s) of the community; and Representative(s) of the relevant Regulatory Agencies.

Capacity building forums with the IBCs are held annually because IBCs play a critical role in advancing innovations in biosciences in Kenya. Their essential functions are to:

- 1. Facilitate G.M. applications preparation
- 2. Advise institutions on Biosafety matters

- 3. Assist institutions in establishing monitoring plans for biosafety risk assessment and management
- 4. Ensure compliance with NBA approval conditions
- 5. Review and ascertain suitability of containment (Physical & Biological)
- 6. Advise institution & Principal Investigators on mitigation measures in case of an accidental release

Currently, the institutions with active GMO projects are; Kenya Agricultural & Livestock Research Organization (KALRO), International Livestock Research Institute (ILRI), International Centre of Insect Physiology and Ecology (ICIPE), Kenyatta University (K.U.), and Masinde Muliro University of Science and Technology (MMUST).



The NBA technical team and the Institutional Biosafety Committee (IBC) members in a group photo during the capacity-building event at the Movenpick Hotel, Westlands- Nairobi.



## **BIOSAFETY NEWS**



GM Cassava harvest at the Confined Field Trials in Kandara, Murangá / Photo Courtesy of ISAAA.

#### **CONTACTS**

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NBA is ISO 9001:2015 Certified