

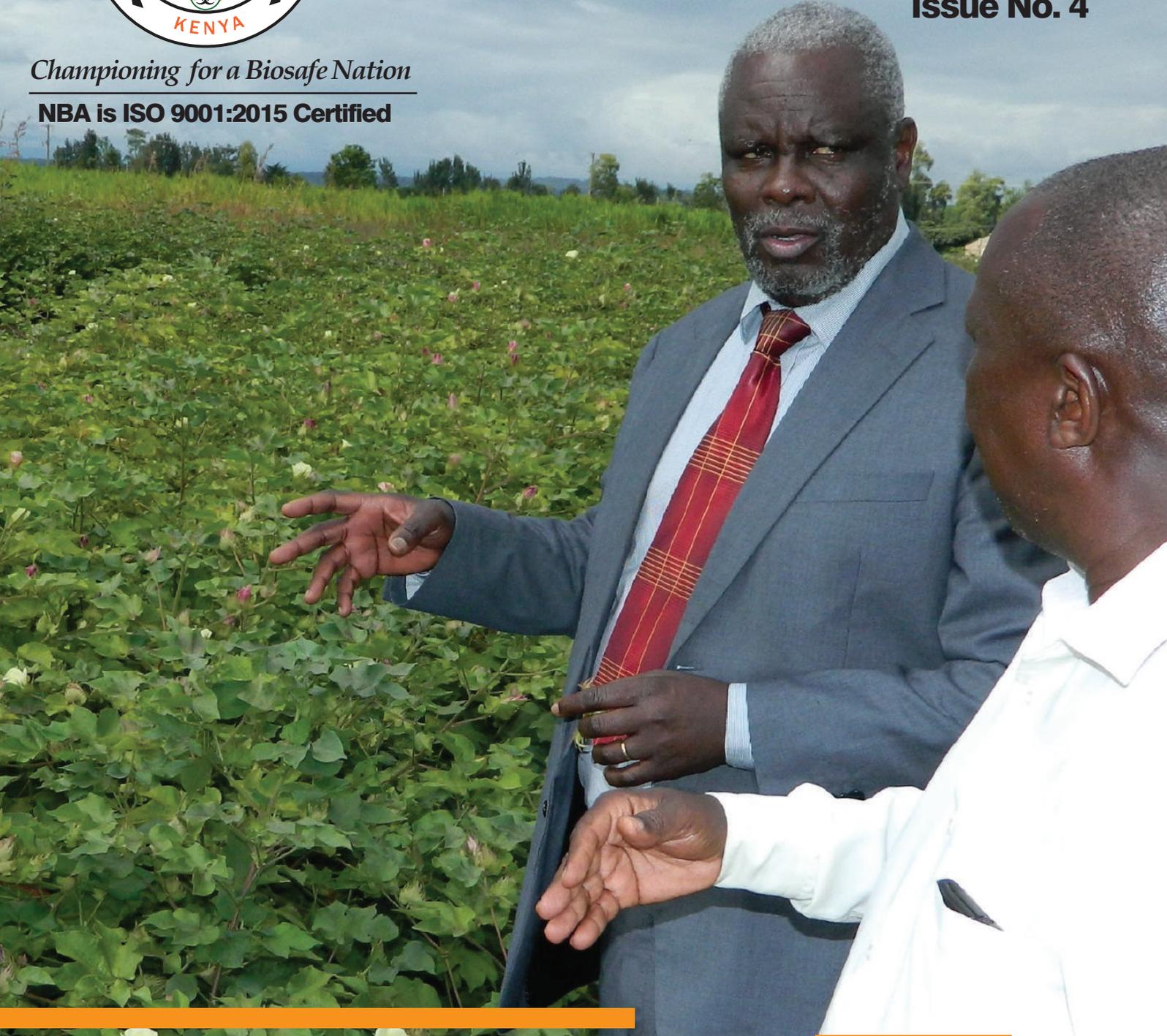


Biosafety News

Issue No. 4

Championing for a Biosafe Nation

NBA is ISO 9001:2015 Certified



**Commercialization of Agricultural Biotechnologies
to achieve the Big Four Agenda**

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Bt Cotton inspection at KALRO National Performance Trial site at Mwea in Kirinyaga County.



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- Editor's Note -

Dear Readers,

It is my pleasure to introduce our Biosafety newsletter from the National Biosafety Authority (NBA), Kenya. This newsletter consists of contributions from our team. We hope you like the new design, format, and new ways of sharing emerging discoveries and news with you.

NBA is a state corporation in Kenya established in 2009 and mandated to ensure the safety of human and animal health and provide adequate protection of the environment from harmful effects that may result from genetically modified organisms (GMOs). Our newsletters will inform and inspire you on the latest developments in biosafety matters in Kenya.

For this issue, the theme is "Commercialization of GMOs to achieve the Big Four Agenda." As you are aware, the big four Agenda in Kenya are; Manufacturing, Food Security and Nutrition, Affordable Housing, and Universal Health Coverage. Of these, manufacturing and food security and Nutrition are directly influenced by the availability of raw material from the agricultural sector.

Consequently, in this newsletter Issue, we will know more about Kenya's capacity to ensure genetically modified organisms are safe for use, the emergence of genome editing technologies in crop improvements, and their regulations. We explore the contribution of genetically modified organisms to Kenya's big four Agenda as well as boosting the Big Four Agenda via Biotechnologies. Plus, the status of the latest GMO applications and approvals at NBA.

As an authority, we acknowledge the fact that COVID-19 had disrupted the normal ways of conducting businesses universally and, subsequently, vastly changed our plans and typical ways of operation.

“ In this newsletter Issue, we will know more about Kenya's capacity to ensure genetically modified organisms are safe for use ”

Undeniably, the pandemic ushered in new approaches towards organizing conferences and many other events. This was evident when the Authority held, a first-ever virtual public participation for open field cultivation of virus-resistant Cassava (VIRCA) in Kenya.

Also, the 9th Annual Biosafety Conference was conducted virtually. The conference presented a unique forum for engaging stakeholders on strengthening Biosafety Systems towards commercialization of GMOs for economic development in Kenya.

Enjoy the read!

Abook Brian,
Editor

MESSAGE FROM THE CHIEF EXECUTIVE OFFICER



Prof. Dorington Ogoji,
CEO, NBA

Establishment of Functional Biosafety Regulatory Frame Work In Kenya

able process of review

- Decision making Process by the Board of Directors (BOD)
- Communication and consultation with the public and relevant stakeholders
- Monitoring for compliance with Approval conditions
- Establishment relevant capacity within and contracted to carry out the functions Under on the Biosafety regulatory system in the Country, a number of research projects have been carried out towards improvement of crops and animals to address constraints in productivity. To-date, the Authority has approved 32 laboratory and 14 confined field trial GMO projects that are being undertaken in various research and academic institutions in the country. Among the crops that have reached field experimentation include; cotton, maize, sorghum, cassava, sweet potato, banana and gypsophila flowers; (<https://www.biosafetykenya.go.ke>). Two products, namely insect resistant maize (Bt maize) and insect resistant cotton (Bt cotton) were approved for limited environmental release in 2018.

“The GM products, once approved by the Authority, are supposed to be clearly labeled as “Approved GM Product” for consumer information and ease of traceability”

The Bt cotton has since been subjected to National Performance Trials and Variety release process and is currently undergoing on farm demonstration. The approval of Bt cotton Environmental release and placement in the market was facilitated by the Cabinet decision to approve the cultivation of Bt cotton on 19th December, 2020. The National Performance Trials for maize has already been initiated in a number of maize growing ecological zones.

The approval for environment Release

follows a rigorous process that involves the following sequential steps; i) screening for Application’s completeness and acknowledgement of receipt; ii) engagement of independent biosafety experts to review food/feed safety, environmental and ecological safety as well as socio-economic data on the application, iii) review of the application by other relevant Government bodies; iv) public participation; v) review of application by a Technical team of the NBA Board and finally a decision is made by the Board.

The GM products once approved by the Authority are supposed to be clearly labeled as “Approved GM Product” for consumer information and ease of traceability. Once in the market, the Biosafety Act provides for post commercialization monitoring and general surveillance for twenty years by the Authority. During the monitoring period and at any stage of use, if any un-intended effect attributed to the released GMO is noted, the product shall be recalled from market immediately. It should be noted that NBA assesses the safety of the GM ingredient and once this is done, the product is subjected to existing assessment as any other conventional product.

With regards to the leading GM crop, Bt cotton that will soon be in the farmers’ field for cultivation, the Authority wishes to assure the public that the products have undergone the full safety assessment and cotton fibre, cotton cooking oil and derived animal feed cake is as safe as products derived from the conventional cotton based on the safety assessment carried out by the Authority.

I take this opportunity to thank the Editorial team for the E-newsletter for the excellent work they have done, let us keep it up! For the stakeholders, I welcome you all to read the E-newsletter which provides highlights on some of the activities that the Authority has made as we deliver on our mandate.

Prof. Dorington O. Ogoji
CHIEF EXECUTIVE OFFICER
NATIONAL BIOSAFETY AUTHORITY

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 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 objects 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 her mandate by ensuring that the country has a functional Biosafety regulatory framework as envisaged in the Act. Among the key parameters for a functional Biosafety regulatory framework include establishment of the following functions;

- Administrative processing of applications and existence of an effective Institutional arrangement
- Transparent, Science based and predict-

Bt-Cotton is the Key to Revitalization and Revival of Cotton Sub-sector in Kenya

By Prof. Theophilus M. Mutui, PhD, NBA Rep., The National Steering Committee

Background:

The Cabinet Secretary (CS) for Agriculture, Livestock, Fisheries, and Cooperatives on 29th April 2020 appointed a National Steering Committee (NSC) on the Implementation of Revitalization and Revival of Cotton Value Chain vide a Kenya Gazette Notice No. 3375 dated 4th May 2020. The Committee is answerable to CS with following Terms of Reference (TOR):

(a) Undertake a quick review of the enabling legal and regulatory framework for their adequacy in supporting revitalization of cotton and pyrethrum value chains in the country;

(b) Undertake an evaluation of the milestones already undertaken and the planned activities and advise CS on the

adequacy of the proposed road map for revitalization and revival of cotton value chains;

(c) Undertake an objective task risk assessment on the revival and revitalization of cotton and pyrethrum value chain, develop appropriate mitigation plans;

(d) Building on the steps already undertaken, map out cotton growing counties and developed a phased out cotton revitalization and revival road map commencing with the most potential counties;

(e) Develop log frame matrix for revival and revitalization of cotton with specific, time bound, realistic and objectively verifiable activity schedules, budgets and indicators;

(f) Undertake monthly briefings to CS on

milestones covered in the revival and revitalization of cotton value chain, the tasks ahead, anticipated challenges and policy matters that require his attention; and (g) Undertake any other task assigned by the CS.

The Committee could not commence working immediately due to the COVID-19 pandemic and restrictions imposed by the Ministry of Health. The inaugural meeting was held on 4th June 2020 at Agriculture Food Authority (AFA) head office in Nairobi. The cotton value chain was identified as critical in supporting Big Four Agenda. Consequently, the Ministry of Agriculture, Livestock, Fisheries, and Cooperatives initiated activities and practical steps for accelerating the revival and revitalization of the Cotton value chain. The Ministry rolled out a pilot program for the revival of cotton by supplying seeds to identified counties in Nyanza and Western Kenya for March / April 2020 rain season.

Policy Principles

1. The NSC categorized the cotton-growing counties into 8 Clusters; Western (Busia, Siaya & Bungoma), Nyanza (Kisumu, Homa Bay & Migori), North Rift (E/Marakwet, Baringo, W/Pokot & Turkana), South Coast (Kwale, Taita Taveta & Kilifi), North Coast (T/River & Lamu), Lower Eastern (Kitui, Makueni & Machakos), Upper Eastern (Muranga, Meru, Embu, Kirinyaga & T/Nithi), and Upper Upper Eastern (Marsabit, Isiolo & Laikipia).

2. The NSC adopted a principle of offering a mix of Bt-cotton, Hybrids, and Conventional seeds options. Initially, Bt-cotton and other Hybrid seeds will be imported by the Fiber Directorate of AFA to be availed free of charge to farmers for planting 15,000 acres and purchase local conventional cotton seeds to plant 10,000 acres. This is for October 2020 short rains in both lower



Inspection of the Bt-cotton trials at KALRO, Mwea, by Dr. Martin Bundi from the National Biosafety Authority.



Eastern and Upper Eastern Clusters and March / April 2021 rains season in Western and Coast Clusters.

3. In the short/medium term, the Kenya Agricultural and Livestock Research Organization (KALRO) is to be supported to enhance its capacity to conduct research on local open-pollinated and hybrid cotton seeds to ensure local availability of affordable quality seeds. This will ensure the sustainable security of quality seeds and independence from imports.

4. To establish six new modern ginneries in Kwale, Embu, Bungoma, Homa Bay, Lamu, and Laikipia as well as modernizing one ginnery in the Western Cluster (Busia County).

5. To engage Private Sector Support in the provision of ginning facilities in clusters where Public / Union Ginneries are not available or planned. These include; Mwea (Upper Eastern Cluster), Malindi (North Coast Cluster), Makueni & Kitui (Lower Eastern Cluster), and Salawa (North Rift Cluster) Ginneries. Where needed, a credit guarantee by Government may be provided to modernize their ginning technologies.

6. Training of Extension Officers who will train farmers (TOTs) by KALRO to cover all the cotton growing clusters.

7. To establish new Cooperatives or strengthen existing ones through capacity building on governance issues in all the cotton-growing clusters.

NSC-County and other relevant Stakeholders Engagements

Members of the Cotton sub-committee visited Coast and Eastern cotton-growing clusters for County and other Stakeholder engagements between 24th August to 4th September 2020. The Counties in the South Coast cluster and upper eastern welcomed the proposal of establishing

new ginneries to serve the clusters, while the lower Eastern cluster (Kitui) embraced the private sector ginneries in the revival strategy. It was observed that existing ginnery in Kitui operates under old technology with low capacity and needs to be upgraded to enhance processing capacity. There is a need to develop a policy on ownership and management involving National, County governments, and other stakeholders (cooperatives and unions) as well as coordination of inter-county engagement within clusters. With the anticipated increased production, there will be a need to consider enhancing capacity to process seed cotton through a Public-Private Partnership (PPP) involving National, County Governments and private Investors in the existing ginneries (Kitui, Makueni, Mwea, Malindi).

The farmers in Eastern and Central Clusters requested to be urgently supplied with Bt-cotton seeds latest by the end of September 2020. Therefore, AFA was to immediately initiate the process of importing 24MT Bt- seeds, and the purchase of 60MT conventional seeds. The NSC is of the opinion that County Governments should support farmers with land preparation and other inputs (pesticides). The Counties expressed the need for immediate training of extension service providers in new skills in order to enhance cotton management. Counties were to immediately nominate adequate staff for training and to allocate resources to recruit extension workers and facilitate their outreach to farmers. There is also a need to sensitize county governments on the National internship program administered by Public Service Commission. Generally, it was observed that farmer organizations (Cooperatives) are the weak link in the cotton revival strategy. Therefore, there is a need to establish new or strengthen existing ones. The cotton farmers will be mobilized to form groups and transit them into cooperatives. The new and

existing cooperatives will be trained in both management and good corporate governance as well as how to develop strategic and business plans. They should comply with the Cooperative Societies Act and Regulations.

Conclusion

The AFA placed order for 40 MT Bt-cotton seed to be imported in October 2020 and is expected to arrive in late October or early November 2020. The Daily Nation of 5th October 2020 carried a Notice by the National Environment Management Authority (NEMA) on the Environmental Impact Assessment (EIA) Study Report for proposed Bt-cotton commercialization. The public is encouraged to submit their comments for 30 days (expiry 4th November 2020). It is expected that NEMA will issue a permit for commercial cultivation of Bt-cotton, which will be the game changer in cotton production in Kenya.

Cotton cultivation has the potential to employ 10 million people and provide income to farmers' that, in turn, provide food security, thus reducing poverty. The cotton demand for the domestic market stands at 140,000 bales annually, whereas production has declined from a peak of 70,000 bales in 1986 to 10,000 bales in 2018. Also, the potential land for cotton growing is 400,000ha but only about 25,000ha is being utilized. In the 'Big Four' agenda, the Government will support the textile industry via increased cotton cultivation using Bt-cotton seeds as well as hybrids. In addition, the Government will train 50,000 youths and women to be involved in Bt-cotton growing. It is expected these interventions will increase revenue from Sh3.5 million to Sh200 billion, create directly 500,000 jobs, and another 100,000 from the apparel sector by 2022, thus restoring the lost glory of the Kenyan cotton industry.

A major milestone: NBA holds first-ever public participation for open field cultivation of virus-resistant cassava in Kenya

During the COVID-19 pandemic, various organizations and the tech industries are finding different ways to navigate the outbreak. In this innovation journey, the National Biosafety Authority (NBA) was not left out. The Authority held its first-ever online public participation for open field cultivation and placing on the market of genetically modified cassava that is resistant to Cassava Brown Streak Disease (CBSD), a common viral disease present in Kenya.

The application was submitted by Kenya Agricultural and Livestock Research Organization (KALRO). According to the applicant and based on data obtained from research conducted so far, the cassava has high levels of disease resistance as a result of the genetic modification. Farmers and consumers will benefit from CBSD resistant cassava as a result of increased cassava root quality and marketable yield.

As required by the provisions of the Biosafety Act No. 2 of 2009, NBA held the public participation forum aimed at getting public comments on the application on 10th June 2020. There was commendable public participation with more than 300 exclusive participants registering to follow the event via Zoom webinar. There were about 113 Google forms submitted with various comments, and more than 200 unique feedback SMSs

received from the public. On Facebook, as one of our social media platforms, the event reached more than 7,500 participants and had about 530 engagements.

The Authority will make a final decision on the application based on environmental and food safety assessment, socio-economic considerations, comments from relevant regulatory agencies, independent experts and relevant comments received from the public.

In the event that the Authority decides to approve the application, official release and commercialization of the cassava seed and plant varieties in Kenya shall apply as per the existing national policy, legislation and guidelines for handling genetically modified crops and new crop varieties.

We take this special opportunity to thank the public and our development partners for the participation and submission of comments.

Biosafety Kenya was live.
Published by Irene Kamau Migwi · 10 June ·

We are Live Now

Processing Applications for Environmental Release

Screening Technical Review Decision Making

Application NBA Secretariat RAS Expert Reviewer

Completeness & Accuracy Acknowledge: 30 days

13:32 / 2:39:07

7,572 People reached 530 Engagements

Boost post

Prof. Mutui from NBA, making a presentation to the public during the Zoom Webinar for VIRCA public participation on 10th June 2020. The event was live on NBA Facebook page.

NBA holds 9th Annual Biosafety Conference

Kenya has made tremendous strides in the advancement of agricultural biotechnologies. Yet, one of the most limiting challenges towards biotechnology development has been the low level of public awareness on biosafety matters. As a result, the National Biosafety Authority held its 9th Annual Biosafety Conference on 12th November 2020. The chief guest for this year's Conference was Amb. Simon Nabukwesi, Principal Secretary - State Department for University Education and Research, Ministry of Education.

With the theme: "Functional Biosafety Systems towards Commercialization of Agricultural Biotechnologies for Econom-

ic Development in Kenya", the Conference came at an excellent time. It presented the perfect opportunity to highlight the remarkable contribution that agricultural biotechnologies have made in many areas of our lives and Kenya's Economic Development. Also, it was one of the ways of enhancing biosafety awareness in the country and exploring ways of addressing the country's Big 4 development agenda.

The fascinating thing about this year's annual biosafety conference is that, unlike the previous ones, it was virtual thanks to the COVID-19 pandemic. The event commenced with the Genome

Editing Workshop that ran for two days; from 10th to 11th November 2020.

As an organization, we take this opportunity to thank the attendees and participants for creating time to be with us and sharing their knowledge and vast experiences. We also wish to thank the National Government and our development partners; BAYER Kenya- Crop Sciences, AUDA-NEPAD, CORTEVA Agriscience, CIMMYT, AFSTA, IPBO, and Plant B&B for supporting this year's Conference with both financial and technical support.

Biosafety Kenya was live.
Published by Abook Brian · 11 November at 13:33 · 🌐

WORKSHOP ON GENOME EDITING TECHNOLOGIES IN KENYA (Day 2)

The National Biosafety Authority (NBA) is a state corporation in Kenya mandated to ensure the safety of human and animal health and provide adequate protection of the environment from harmful effects that may result from genetically modified organisms (GMOs).

This workshop will have the following sessions:... [See more](#)

November 2019:

The European Council, the EU's leading political body, has asked the EU Commission to clarify how "novel genomic techniques" are to be legally classified and regulated in the future. The results of this study are to be presented by April 2021 - including proposals and an impact assessment.

2:08:13 / 3:46:16

873 People reached 169 Engagements [Boost post](#)

Dr John Komen, the Assistant Director- Program for Biosafety Systems (PBS), giving a virtual presentation on the global perspectives of regulatory approaches to genome editing. The Conference was live on NBA Facebook page.

The status of latest GMO Applications and Approvals at NBA

By Julia Njagi

The latest projects to be approved by the Authority for contained use include an application by the International Livestock Research Institute (ILRI). The contained use activity involves screening of transgenic LR34 and LR67 sorghum genotypes against anthracnose disease. The two transgenes, i.e. Lr34 and Lr67, were introduced into sorghum using particle bombardment mediated transformation method.

This was the preferred method to *Agrobacterium*-mediated due to a history of higher success rates than when the former was used to transform sorghum. Microprojectile overcomes two hurdles, i.e. the difficulty to regen-

erate plants when protoplasts are used and the lack of a viable natural vector such as *Agrobacterium tumefaciens*.

Among the major constraints to sorghum production are diseases, most notably, fungal diseases including anthracnose, which has been identified as one of the most devastating and most important diseases infecting sorghum in East African countries. The overall objective of this research is to screen local sorghum varieties alongside genetically modified ones harbouring the sugar transporter genes (Lr67 and Lr34) against anthracnose races collected from Kenyan hotspot Alupe and isolated at ICRISAT laboratories in Nairobi.

A second application involving screening of genome-edited sorghum lines (LGS1 loci) for resistance against Striga (*Striga hermonthica*) was approved to be carried out within the plant Transformation Laboratory (PTL), Kenyatta University, Main Campus.

Striga is a parasitic weed which attaches to roots of cereal crops, siphons the nutrients leading to severe retardation and death of the host plant. Striga is difficult to control because of its ability to produce a large number of seeds that remain dormant in the soil for long periods, only germinating in the presence of a suitable host crop. It is now understood that germination stimulant



NBA-KEPHIS Joint Inspection of the Plant Transformation Laboratory & Green house at Kenyatta University before the Commencement of the Striga Project.

is a hormone called strigolactone. Furthermore, it is also now known that some sorghum varieties have a natural mutation in the loci called Low Germination Stimulant 1 (LGS1) that prevent them from producing the germination stimulant strigolactone. On this understanding, scientists at Corteva Agrisciences (USA) collaborating with Kenyatta University used genome editing technology based on CRISPR/Cas9 to precisely introduce mutations in a farmer popular sorghum variety called Marcia (that is susceptible to Striga) in the LGS1 loci. The objective of the contained use is to evaluate the

effectiveness of the genome-edited sorghum lines (LGS1 loci) in conferring resistance to Striga.

Any person intending to undertake any activity involving GMOs has to apply to the NBA for approval using the prescribed forms (available in the NBA website <http://www.biosafetykenya.go.ke>). NBA alongside other relevant regulatory agencies and independent experts undertake safety assessment of the GMOs to ensure safety to humans, animals and the environment and a decision made between 90-150 days. Application for approval is given by the NBA Board following a thorough risk

assessment process and after ensuring that the proposed risk management measures put in place are acceptable.

The Authority is also expected to inspect and certify all facilities (laboratories, greenhouses, and confined field trial sites) involved in GMO research in Kenya. Once NBA approves GMO projects, it undertakes continuous monitoring to assess compliance to Biosafety laws and approval conditions. The Authority has powers to suspend or revoke any approved GMO project where the person granted such an approval is in contravention of the conditions imposed.

GALLERY



NBA staff members in a group photo during the meeting to develop the 2020 - 2025 NBA Strategic Plan in Naivasha, Kenya.

National Biosafety Authority CEO, Prof. Dorington O. Ogoyi (3rd from left), receiving the submissions for the GM Cassava application from ISAAA and KALRO representatives.



A group photo of the team site visit for inspecting the Confined Field Trials (CFT) demonstration of Insect Protected Bt-Maize Hybrids in Kitale.



National Biosafety Authority CEO, Prof. Ogoyi (Left), inspecting the Bt-cotton Trials at KALRO- Mwea.



Flattening the Covid-19 Pandemic Curve: NBA's Contribution

By Dr. Martin Bundi, Secretary - Work Safety and Environmental Committee

The COVID-19 (Coronavirus) pandemic has affected day-to-day life, businesses, world trade, and movements resulting in significant effects on the global economy and healthcare. In Kenya, the first reported case was on 13 March 2020.

To curb the spread of the pandemic and enable the recovery of the economy, Kenya enacted various measures, including limiting movement in places with reported cases, limiting the number of people in social gatherings and public events, dusk-to-dawn curfews, and ensuring basic hygiene and social distancing. Policies towards the same have been published.

1. As a way of ensuring employees and clients safety at the same time allowing for business continuity, the National Biosafety Authority (NBA) has instituted the following measures towards COVID-19 prevention and control at the workplace: Institution of a monthly duty rota covering minimum personnel numbers during all working hours to ensure business continuity.



An NBA staff member using one of the touch-free sanitizer dispensers installed at the reception.



National Biosafety Authority Staff members sitting two meters apart at the workplace.

2. Provision of a safe and hygienic work environment buying PPEs made in Kenya to create jobs; provision of KEBS approved face masks for staff, cleaners, and clients; installation of hand sanitation devices (hand washing and sanitizers) and maintaining a clean work environment.

3. Automation of Authority's services for efficient service delivery resulting in less paperwork and reduced physical office visits, which may cause crowding.

4. Use of electronic (emails, websites, social media) correspondence methods to avoid paperwork and reduce cost.

5. Promotion of social and physical distancing; the arrangement of office work desks two meters apart and ensuring clients keep a social distance.

6. Holding of virtual meetings: encouraging holding of virtual meetings whenever participants are more than four, and the available space does not allow for social distancing.

7. Promotion of staff capacity building: staff members have been attending several virtual meetings, including those for skills development, PC process, Biosafety meetings (e.g., FAO GMO food safety workshops, Genome editing, Gene drives, etc.) as well as the planned virtual Biosafety conference.

8. Continual staff sensitization on COVID-19 and preventive measures: staff sensitization on Ministry of Health's directives on COVID-19, measures instituted at NBA, proper donning and doffing of PPE, among others.

9. Voluntary COVID-19 testing at a subsidized cost for staff members: The Authority has entered into an agreement with various health providers through the contracted health insurance firm to facilitate voluntary COVID-19 testing of staff.

NBA Staff Named Global Biosafety Mentor

Dr. Martin Bundi, a Principal Biosafety Officer at NBA, has been conferred as a Global Biosafety Mentor by the International Federation of Biosafety Association (IFBA). IFBA's Secretariat announced on 28th July 2020 following a global recruitment process. Martin joins other biosafety professionals in the 2020-2021 program cycle who will be paired with mentees in their areas of profession to offer professional guidance in various biosafety fields including biosecurity; biorisk management; biological waste

management; biocontainment facility design, operation, and maintenance; and biological safety cabinets selection, proper use, and maintenance.

The mentorship program provides regionally and culturally relevant professional support and ultimately encourages sustainable interregional biosafety and biosecurity networks. Mentees are nurtured on various aspects of biosafety and biosecurity and other career development skills while mentees get an opportunity to

pursue additional professional certifications from IFBA.

Martin is an IFBA certified professional in biosecurity and in Biorisk management. He has research experience on enteric infectious diseases in Kenya. He continues to support the Kenya Medical Research Institute (KEMRI) in the training of new biosafety level 3 users in laboratory biosafety and biosecurity management.



Dr. Bundi giving a lecture during the Biosafety training Workshop for the Third Country Training Program (TCTP) at KEMRI in October 2019.

Dr Bundi during the demonstration of donning and doffing PPE.



Community Engagements: Donation of padded seats to Kenyatta National Hospital Cancer Treatment Center

NBA relishes Corporate Social Responsibility (CSR) activities. As an organization, we understand that a robust CSR program is an opportunity to demonstrate good corporate citizenship. It is part of our commitment to managing the social, environmental and economic effects of our operations responsibly and in line with public expectations. Also, it forms part of our approach to corporate governance and often touches every aspect of our operations, human resources and safety.

This year, we reinvested in health and safety environmental programs and supporting charitable organizations in the community. We donated four 3-seater padded seats to Kenyatta National Hospital (KNH) Adult Cancer Centre.

NBA benefits from CSR through creating good reputations, attracting positive attention, minimizing environmental impacts, attracting top talents, and inspiring innovation.



NBA Staff members in a group photo before donating padded seats to Kenyatta National Hospital Cancer Treatment Center.



NBA staff members, together with the KNH staff members during the donation exercise at KNH Cancer Treatment Centre.

The emergence of Genome Editing technologies in crop improvements and their regulations

By Mr Josephat Muchiri

Introduction

To date, almost one billion people suffer from prolonged starvation, while at the same time, agricultural systems are degrading fast, aggravated by unpredictable climate change and loss of valuable biodiversity. The global population is projected to exceed 9 billion by 2050. Consequently, current agriculture practices will face enormous challenges, requiring resilient crops with improved yields and better quality and requiring fewer farm inputs. For decades, conventional breeding has been the most widely used approach for crop improvement. This old age crop improvement program faces multiple challenges, among them being labor-intensive, and it usually takes several years from the research phase to release commercial varieties. To address some of these challenges, scientists have devised modern techniques to improve crops quickly, and one of them is a genetic modification invented in the 1970s.

Both conventional breeding and genetic modification lead to improved crops' traits, the difference being the approach employed. While conventional breeding utilizes genes solely from the same or closely related species, and their development takes a long time, genetic modification utilizes genes from the same or different species normally in a shorter period. Genetically modified (GM) crops are produced by transferring genes (transgenes) or gene elements of the superior trait into preferred crop varieties. Despite the potential benefits GM crops have for global food security, their adoption is hindered by safety concerns obliging Governments to put stringent measures for their regulation. However, even with these stringent controls, concerns persist among certain segments of the population. This scenario has again triggered the scientific community to devise supplementary technologies that address some of the genetic modification processes' concerns. One notable technology is Genome Editing.

Gene or Genome editing refers to the latest set of techniques for precisely altering plants and animals' genetic makeup. It is a collection of techniques that facilitate precise, efficient, and targeted modifications at the organism's genome level. The main difference between genetic modification (GM) and genome editing is that GM does not predictably allow genetic changes to specific locations in the DNA. In contrast, genome editing enables making precise changes to the DNA. The methods differ, but the goal to improve the foods we eat is the same. The current methods for Genome-editing are grouped into two; Oligonucleotide Directed Mutagenesis (ODM) and Site-Directed Nucleases (SDN). Researchers can delete, add, or change genes on specific regions in the genome using ODM and SDN systems.

Oligonucleotide Directed Mutagenesis involves precisely altering the sequence of a particular genome target(s) by one or more bases. This technique has been successfully employed in bacterial, yeast, mammalian, and plant systems (Aarts et al., 2006; Gocal et al., 2015).

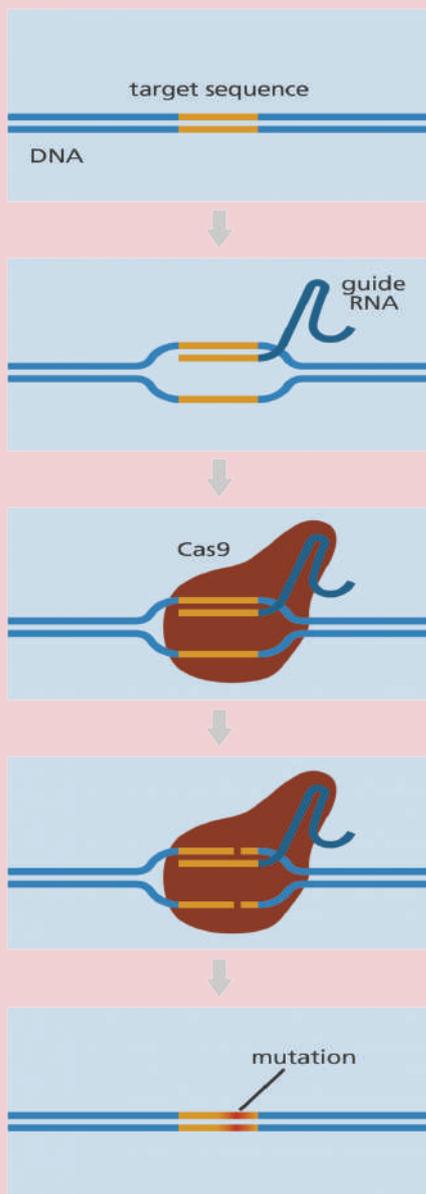
Site-Directed Nuclease (SDN) are sets of techniques based on the use of enzymes called nucleases that introduce a break/cut in the DNA chain near a specific region that is later repaired naturally. Four main classes of SDNs are used in plant genome editing, namely; (1) meganucleases, (2) zinc finger nucleases (ZFNs), (3) Transcription Activator-Like Effector Nucleases (TALENs), and (4) Clustered Regularly Interspaced Palindromic Repeats (CRISPR)/Cas9 nuclease system (Voytas and Gao, 2014). Among the four site-directed nuclease approaches, the CRISPR system is the most widely used technique genome editing technology today.

CRISPR Cas technology makes gene editing faster, more affordable, and more precise and consists of two key molecules that introduce a change (mutation) into the DNA. These are:

- a. Cas9 enzyme (nuclease) acts as a pair of 'molecular scissors.' The Cas 9 enzyme cuts the double-stranded DNA at a specific location in the genome so that bits of DNA can then be added or removed.
- b) A piece of RNA called guide RNA (gRNA), a guiding piece of genetic material. Scientists can create a guide RNA corresponding to any sequence of an organism's genome. gRNA ensures that the Cas9 enzyme only cuts at the right position in the genome.

How CRISPR-Cas9 system works

- The guide RNA is designed to find and bind to a specific sequence in the DNA. The guide RNA is expected to only bind to the target sequence and no other region of the genome. In practice however, it's possible that the cas 9 cuts at a different location leading to off-target mutations which is a leading concern for those who advocate regulation of genome editing technologies.
- The Cas9 enzyme (molecular scissor) follows the guide RNA to the same location in the DNA sequence and makes a cut across both strands of the DNA. At this stage the cell recognizes that the DNA is damaged and tries to repair it.
- Scientists can use the DNA repair machinery to introduce changes to one or more genes in the genome of a cell of interest (<https://www.yourgenome.org/facts/what-is-crispr-cas9>)



CRISPR CAS Gene Editing Technology;
Image credit: Genome Research Limited.

Applications and regulation of genome editing technologies

CRISPR Cas technology is currently being used in several industries that utilize bacterial cultures, medical applications, and crop breeding. One of the main applications of CRISPR Cas in medicine is treating and managing genetic diseases and disorders. At present, the main goal of CRISPR systems in crops is to achieve improved yield performance, bio-fortification, biotic and abiotic stress tolerance, and plant quality enhancement.

In terms of regulatory frameworks on gene editing technologies, discussions are still ongoing at the global level. One school of thought is that genome editing products should not be regulated as

GMOs, while others feel they should be regulated similarly as GMOs. For example, the United States Department of Agriculture (USDA) in March 2018 announced that it would not regulate gene-edited crops, including CRISPR techniques. The USDA's decision applies only to crops from which some genes have been removed or crops to which genes endemic to the species have been added. This editing, USDA opines, is essentially an advanced form of accelerated selective breeding. In the European Union (EU), a ruling made by the EU Court of Justice in July 2018 required the development of plants created by CRISPR technology to go through the same approval process as traditional transgenic plants. However, it does not involve transferring genes between organisms. In Kenya, the Biosafety Act enacted in 2009 was not explicit on regulating these new and emerging technologies, as such a guideline has been developed through public participation of various stakeholders to bridge this gap. In the meantime, research activities involving genome editing are being regulated using the existing Biosafety (Contained Use) Regulations, 2011. To date, the Authority has approved five genome editing applications under containment including, the transformation of banana for resistance against nano-viruses and caulimoviruses, Genome editing of yam for resistance to yam mosaic virus and Anthracnose disease as well as enhanced Vitamin A, Grass pea modified for nutritional and other agronomic traits, development of vaccines for the control of African swine fever virus (ASFV) and trypanosome resistant goat. Two other applications employing genome editing technology, namely; Striga (parasitic weed) resistant sorghum and inducement of an early flowering trait in cassava, are currently under consideration by NBA.

In conclusion, genome editing technologies are transformative tools that can revolutionize biological research and ultimately contribute to the achievement of Kenya's Big Four Agenda, especially those related to food security, manufacturing, and universal health coverage. For instance, emerging technologies have tremendously expanded the ability to manipulate and study model organisms

and support the promise of correcting the genetic causes of many diseases. Genome editing gives hope in agriculture in the production of Genetically Modified crops to improve on their yields and counter extreme conditions such as diseases and drought. However, this technology also raises ethical issues, especially in humans. This calls for a need for regulators and policymakers to develop scientific guidelines that are more predictable and proportionate to the risk of regulating these technologies right from conceptualization to commercialization of the products developed from the genome-editing technologies

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