Biosafety Regulatory Experience in Africa-Emerging Africa Union Policy and Regional Harmonization Efforts

- Science Technology and Innovation, and Regulation for sustainable Industrialization in Uganda, 21-23, 2022

Silas Obukosia (PhD)and Jeremy Tinga Ouedraogo (PhD) AUDA-NEPAD-ABNE, Kenya, Centre of Excellency for Rural Resources and Food System

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Outline of Presentation

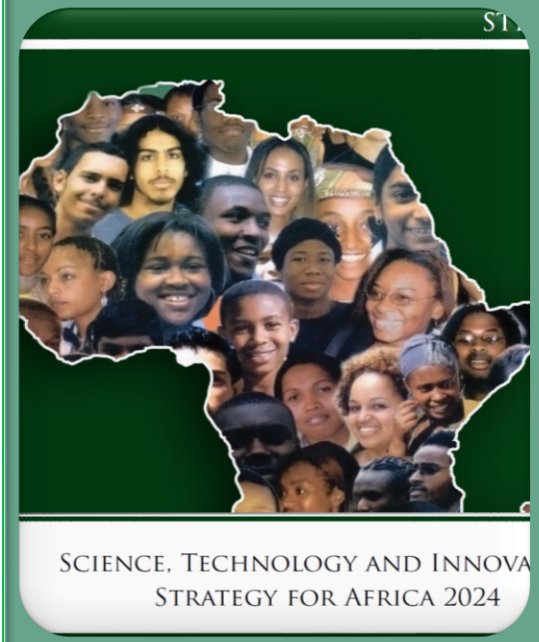
- Functional Biosafety Regulatory Frameworks
- Enabling of Biotech Products-first generation Second Generation
- Emerging Technologies- Genome Editing
- Emerging Technologies- Gene Drives
- Emerging Technologies- Synthetic Biology
- Harmonization Efforts- COMESA, ECOWAS

AGENDA 2063: THE AFRICA WE WANT

Strategic Framework- for socio-economic development of AU members states and has 7 Aspirations and 20 Goals.

Vision of AU-Pan African Vision of *An integrated, prosperous and peaceful Africa, driven by its own citizens, representing a dynamic force in the international* arena

Science Technology and Innovation Strategy for Africa



In June 2014, 23rd Ordinary Session of African Union Heads of State and Government Summit adopted a 10-year Science, Technology and Innovation Strategy for Africa (STISA-2024).

Strategy. Strategy is part of the long-term people centered AU Agenda 2063 which is underpinned by Science, Technology and Innovation as multi-function tools and enablers for achieving continental development goals.

Sectors- agriculture, energy, environment, health, infrastructure development, mining, security and water among others

"Freedom to Innovate"- 2007

Calestous Juma and Ismail Serageldin

Report on Biotechnology and how it can be safety used to spur development in Africa

Key challenges in Africa- where biotechnology to be applied

Food security and nutrition

Healthcare

environment

Identified use of- Agricultural biotechnology, Animal Biotechnology, Health Biotechnology and Forest Biotechnology

Report underspin ensuring Safety in application of Biotechnology Establishment of ABNE in 2008.

Sustainable Development Goals (SDGs)

SDG1. End poverty in all its forms everywhere in the world.

SDG2-End hunger, achieve food security and improved nutrition and promote sustainable agriculture.

SGD 3-Ensure healthy lives and promote well-being for all at all ages.

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Establishment AUDA-NEPAD and Mandates

Mandate, Vision, Mission

In line with AUDA-NEPAD mandate and core functions and towards the objectives of the AU Agenda 2063

AUDA-NEPAD Mandate

Provide knowledge-based advisory services and technical assistance to African Union Member States and regional economic communities to strengthen their capacity

Coordinate and execute priority regional and continental projects enshrined in Agenda with the aim of accelerating regional integration so as to achieve the Africa We Want

Act as the continent's technical interface on policy development recommendation and implementation with partners and stakeholders

Undertake the full range of resource mobilization

The Genesis of Biosafety Frameworks in Africa

UNEP-GEF. 2000 Phase 1- covered 18 countries of which 7 were from Africa- Malawi, Namibia, Uganda, Zambia, Kenya, Malawi, Mauritania, Mauritius, Namibia, Cameroon and was later expanded to 100 countries globally

Program for Biosafety Systems -2005-to "create the infrastructure developing countries need to use biotechnology safely, building policies and capacity for science-based regulations

African Biosafety Network of Expertise (ABNE-2008)- Launched by AUDA-NEPAD as Biosafety Resource Network of Expertise – biosafety resource network for African regulators and policy makers with target of 55 AU Members countries

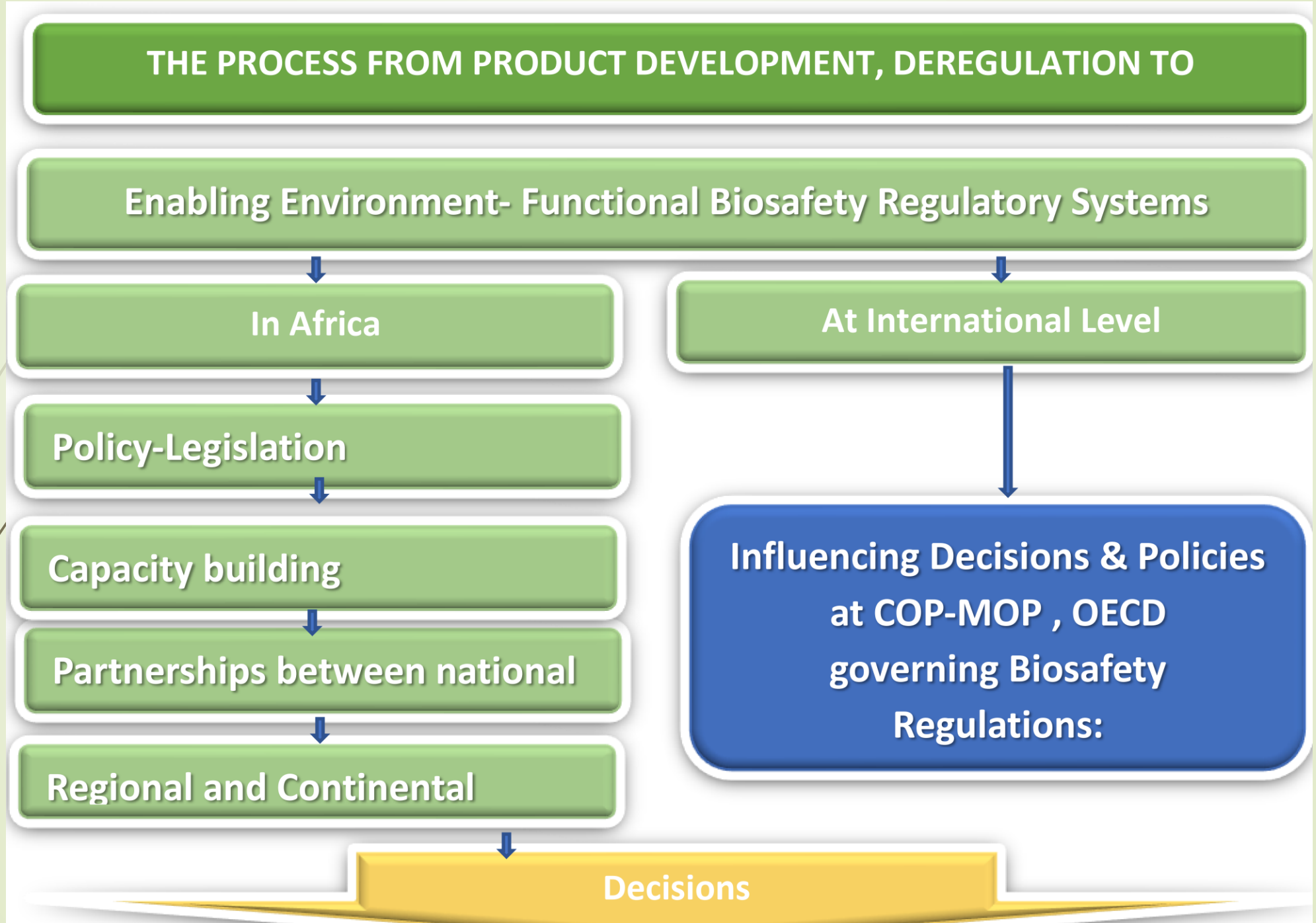
Current Biosafety Landscape in Africa

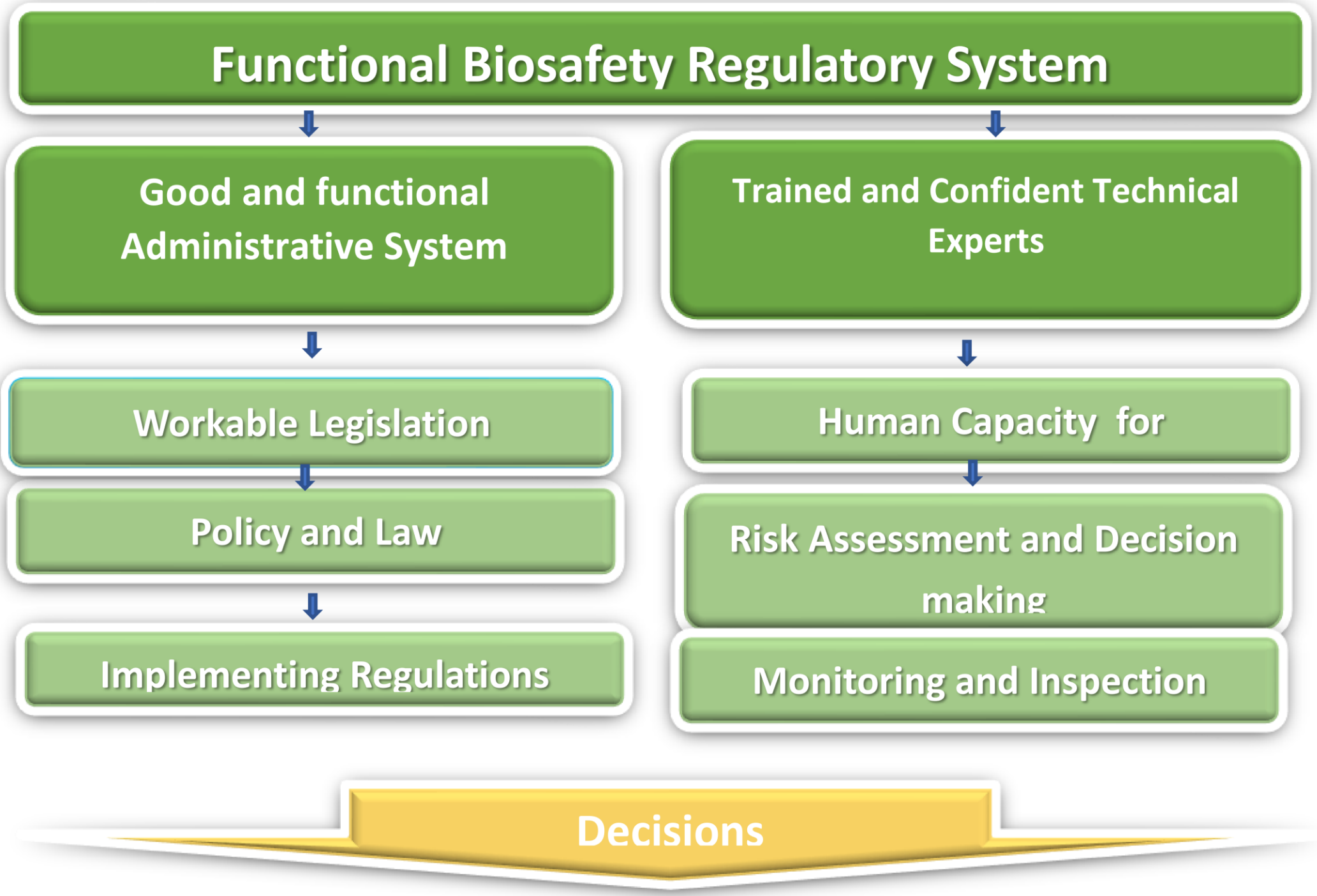
Today 23 Africa Union Members States have Biosafety Acts

28 countries have no Biosafety Acts but are party to the Cartegena Protocol

4 Countries not party to CPB and no legal frameworks- South Sudan, Sao Tome and Principe, Western Sahara

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY


THE PROCESS FROM PRODUCT DEVELOPMENT, DEREGULATION TO
Enabling Environment- Functional Biosafety Regulatory Systems
In Africa
Policy-Legislation
Capacity building
Partnerships between national
Regional and Continental
At International Level
Influencing Decisions & Policies at COP-MOP , OECD governing Biosafety Regulations:
Decisions

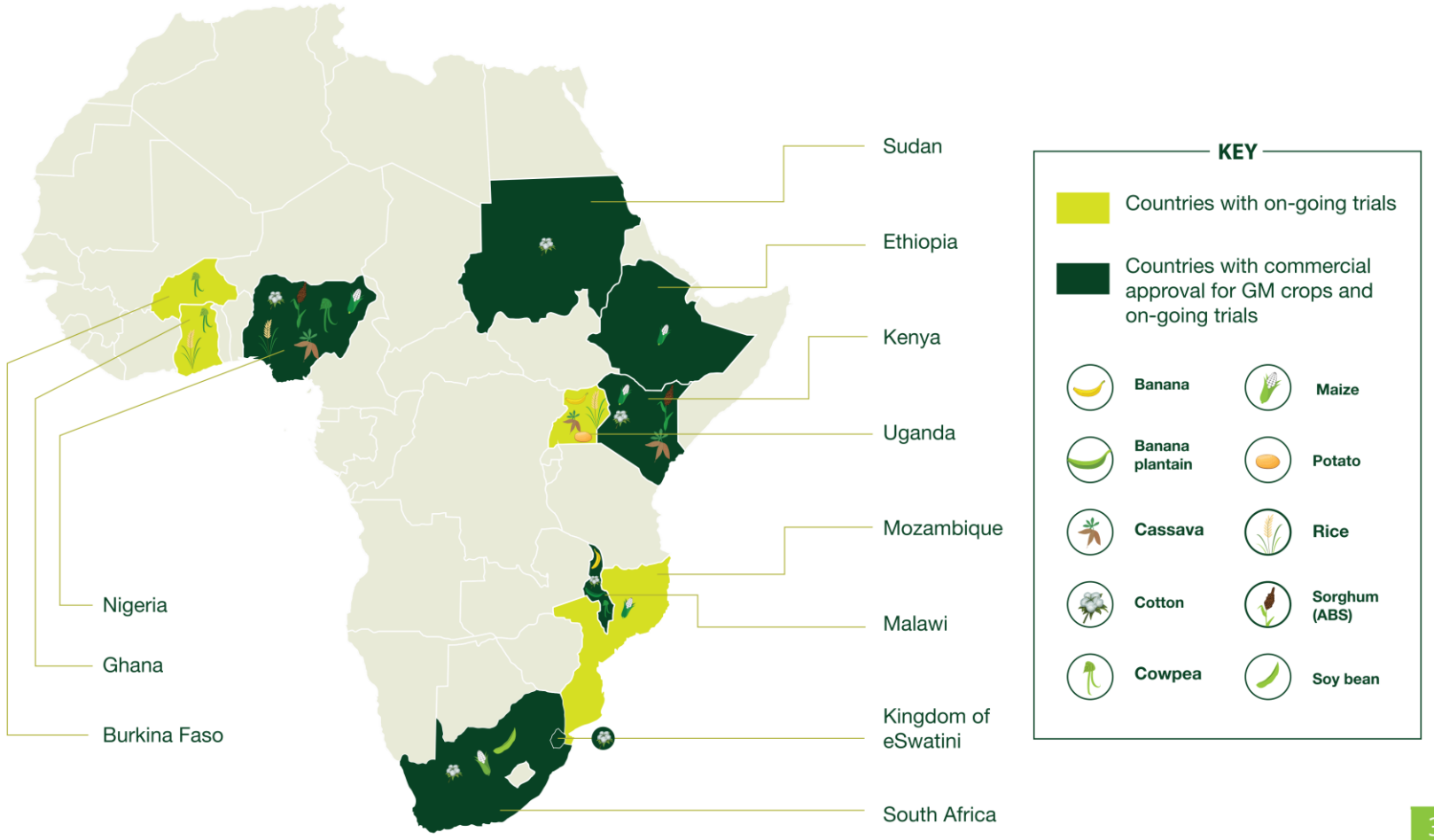

Functional Biosafety Regulatory System
Good and functional Administrative System
Trained and Confident Technical Experts
Workable Legislation
Policy and Law
Implementing Regulations
Human Capacity for
Risk Assessment and Decision making
Monitoring and Inspection
Decisions

Decisions on General Release/Commercialization of Biotech Crops for single traits

ISAAA (2019)

Africa Moving Forward: Biotech/GM Status by 2019

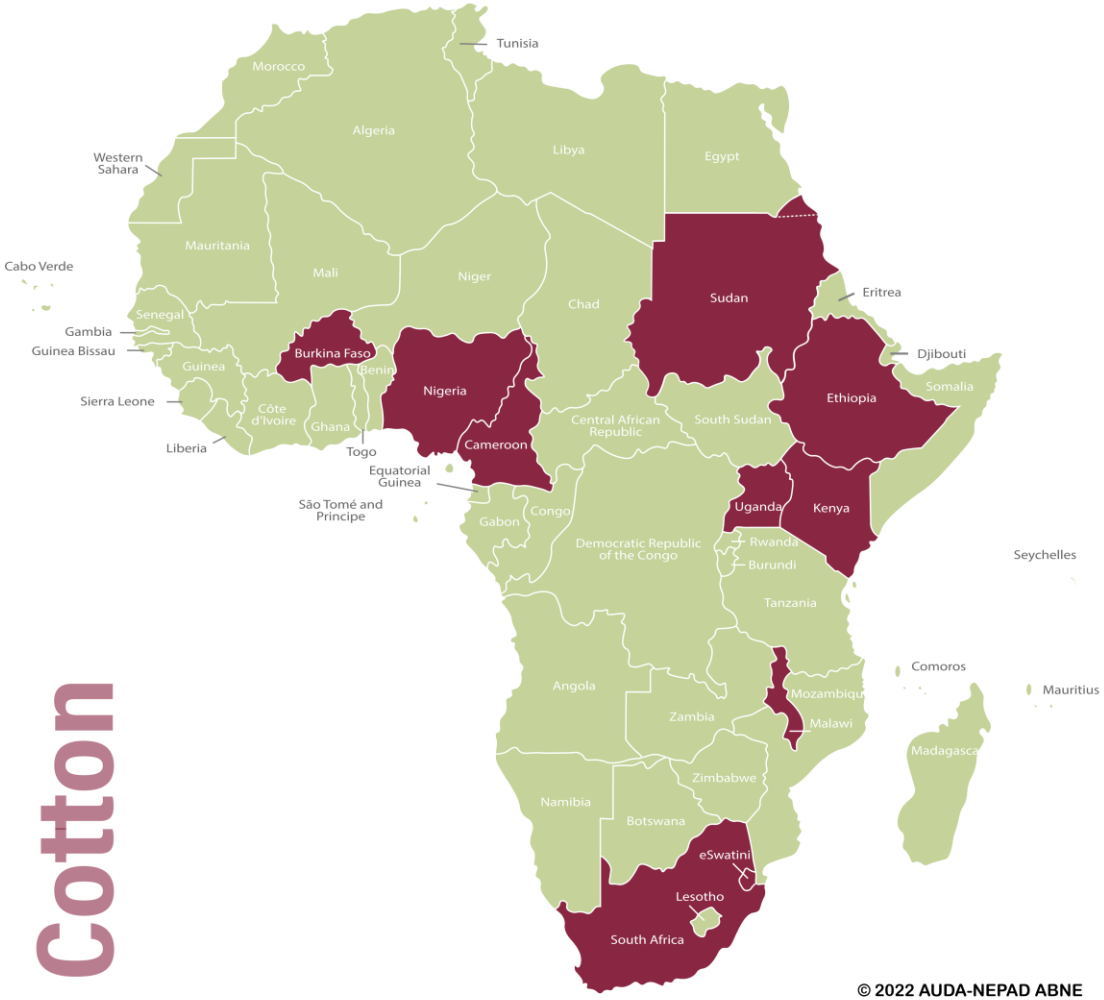
10 CROPS **11** COUNTRIES **16** TRAITS



GM Crops Developed in Africa

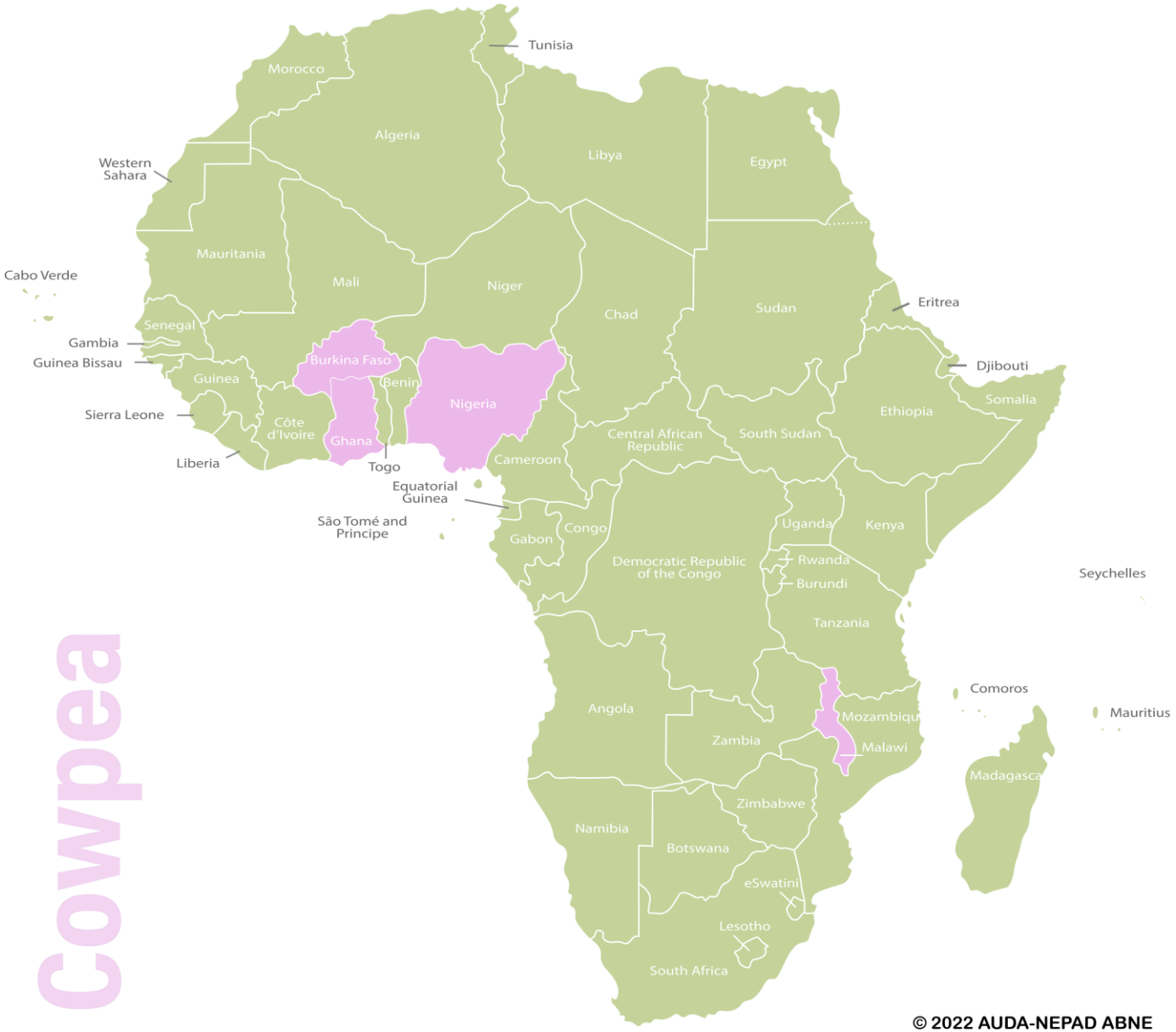
Maize

GM Crops Developed in Africa



Cotton

GM Crops Developed in Africa



Advanced Testing and Commercialization of Biotech Crops with stacked Traits- Need for Guidance Documents

Mon 87460	Mon 89034
Drought Tolerant	**Insect Resistant**
 	 
Event Approval- Food Safety and Environmental Safety	**Event Approval-Safety Data- Food Safety and Environmental Safety**
Stack is Mon 87460 x Mon 89034	
	

Source of karyotype--Silva JC, Carvalho CR, Clarindo WR (2018

Status of testing and approval of stacked traits in Africa

Nigeria

- Enhanced Capacity
- Developed Guidelines
- Commercialized Mon 78460 x Mon 89034

Kenya

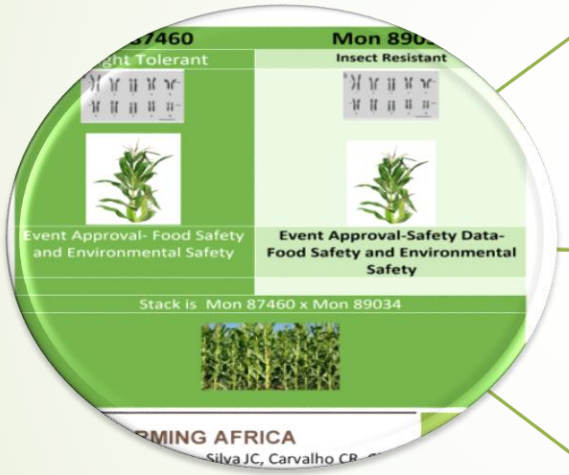
- Enhanced Capacity
- Developing Guidelines
- Testing Mon 87460 x Mon 89034

Ethiopia

- Enhanced Capacity
- Considering General Release of Mon 87460 x Mon 810
- CFT of herbicide tolerant and insect resistant cotton

Malawi-Capacity enhancement

Status of testing and approval of stacked traits in Africa



Mozambique

- Testing Dought tolerant and insect resistant maize (Mon 87460 x Mon 89034)

South Africa

- Soybeans- herbicide tolerant and insect resistants
- Cotton- herbicide tolerant and insect resistant
- Maize- insect resistant and drought tolerant (TELA)

Cameroon

- Cameroon tested under CFT- Insect resistant and herbicide tolerant cotton GlyTol x TwinLink. Interest to eSwatini


GM Crops Developed in Africa
Rice
© 2022 AUDA-NEPAD ABNE


GM Crops Developed in Africa
Potato
© 2022 AUDA-NEPAD ABNE


GM Crops Developed in Africa
Soybean
© 2022 AUDA-NEPAD ABNE


GM Crops Developed in Africa
Banana
© 2022 AUDA-NEPAD ABNE

Africa High Level Panel of Experts on Emerging Technologies

Africa High Level Panel of Experts on Emerging Technologies

Yaye Kène Gassama. Vice Présidente, Académie Nationale des Sciences Techniques du Sénégal (ANSTS) Ancien Ministre de la Recherche Scientifique du Sénégal, Dakar, SENEGAL

Abdallah Daar
Emeritus Professor, University of Toronto, Canada

Berhanu M. Abegaz.
Former Executive Director, African Academy of Sciences, Ethiopia

Francine Ntoumi.
Director, Fondation Congolaise pour la Recherche Médicale, Congo-Brazzaville

Rachel Chikwamba
Vice President/Group Executive at the Council for Scientific and Industrial Research (CSIR), South Africa

Roseanne Diab
Director, GenderInSITE, former Executive Officer of the Academy of Science of South Africa (ASSAf)

Karim Maredia
Professor and Director of the World Technology Access (WorldTAP) Program, Michigan State University (MSU), USA

Oye Ibidapo-Obe
Former Vice-Chancellor, Federal University Ndufu Alike, Ikwo (FUNAI), Nigeria

Shireen Assem
The Agricultural Genetic Engineering and Biotechnology Research Institute (AGERI), Egypt

- Gene drives;
- Drones for precision agriculture
- Microgrids
- Artificial intelligence
- Drones for precision agriculture:
- Urban agriculture
- Synthetic Biology (Gene Editing);
- 3D printing
- Next-generation batteries
- Water purification

MICRO-GRIDS

EMPOWERING COMMUNITIES AND ENABLING TRANSFORMATION IN AFRICA

African Union

NEPAD
TRANSFORMING AFRICA

DRONES ON THE HORIZON

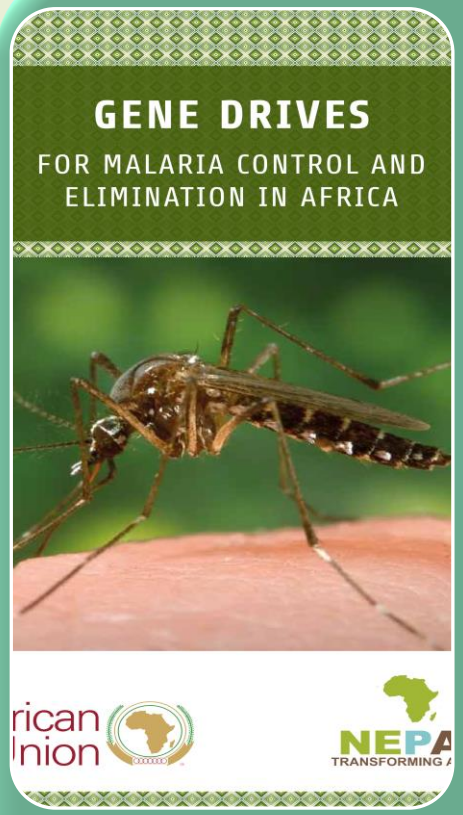
TRANSFORMING AFRICA'S AGRICULTURE

African Union

NEPAD
TRANSFORMING AFRICA

Gene Drives for control and Elimination of Malaria

The Decision, Assembly/AU/Dec.649(XXIX) ASSEMBLY OF THE UNION-



The Decision, Assembly/AU/Dec.649(XXIX) ASSEMBLY OF THE UNION- July 2017 Addis Ababa, Ethiopia. where the Decision on Aids Watch Africa (AWA) Report- states that "The Assembly, COMMITS to sustain the gains made in the fight against Malaria and monitor antimalarial drug resistance and insecticide resistance; **COMMITS ALSO to invest in the development and regulation of the gene-drive technology** as well as other new innovations including next generation insecticides for Indoor Residual Spraying and Long Lasting Insecticidal Nets, Rapid Diagnostic Tests and Artemisinin-based Combination Therapy for the elimination of malaria and REQUESTS the Commission, WHO and NEPAD Agency to support these initiatives (Africa Union, 2017).

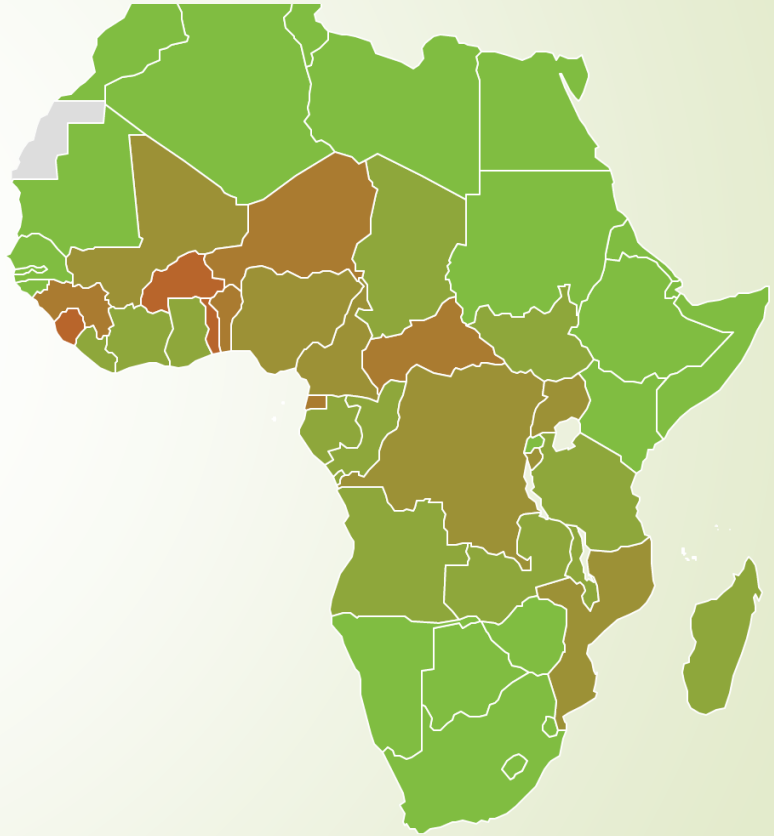
The Malaria Burden in Globally

Every two minutes, a child under five dies of malaria. Many of these deaths are preventable and treatable.

In 2019, there were 229 million malaria cases globally of which 409,000 deaths.

67 per cent (274,000) of deaths were children under 5 years of age.

Malaria in Africa - UNICEF DATA



Percentage of deaths caused by malaria in children under 5 years of age in Africa (2000-2017)

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

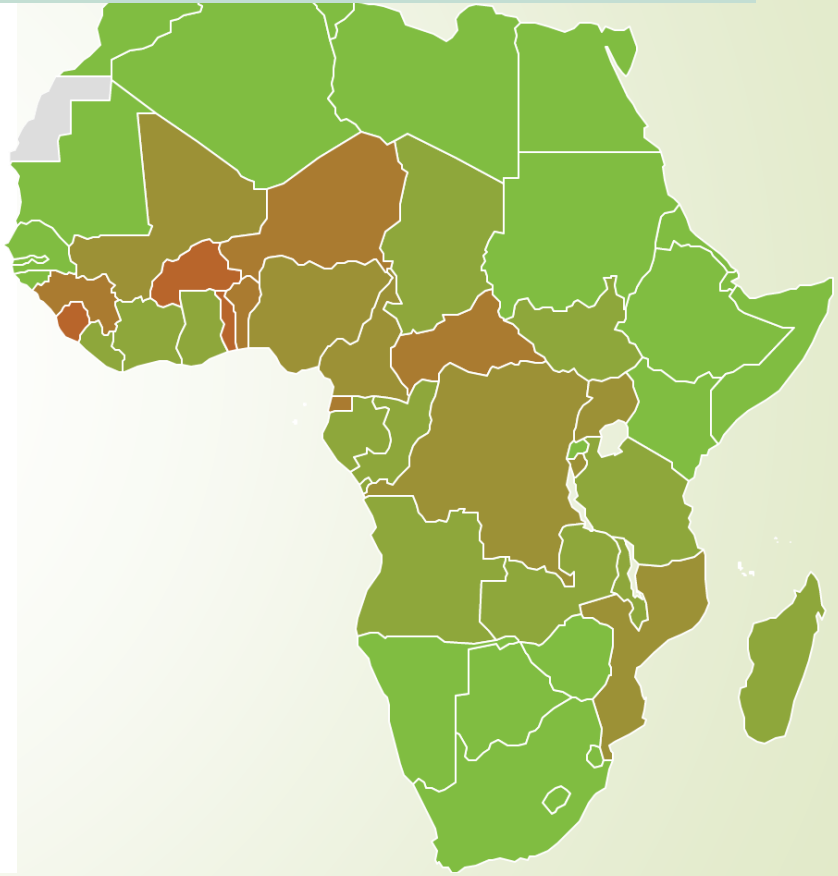
The Malaria Burden in Globally

About 95% of malaria deaths globally were in 31 countries.

Nigeria (23%), the Democratic Republic of the Congo (11%), the United Republic of Tanzania (5%), Mozambique (4%), Niger (4%) and Burkina Faso (4%) accounted for about 51% of all malaria deaths globally in 2019.

Malaria deaths in the WHO African Region reduced by 44%, from 680 000 in 2000 to 384 000 in 2019, and the malaria mortality rate reduced by 67% over the same period, from 121 to 40 deaths per 100 000 population at risk

Malaria in Africa - UNICEF DATA



Source: WHO Maternal Child Epidemiology Estimation 2018

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Lab testing

Confined small-scale field releases

Open small-scale field releases

Large-scale field releases

Physically confined

The transgenic lines bearing these genetic constructs produced and tested in small cages inside the lab

assess safety

Geographically isolated

assess entomological outcomes

Assess disease impact

Malaria incidence

Deployment

Village testing

Gene Drive mosquitoes

Towards Malaria Elimination 2030

Small-scale laboratory studies for efficacy and safety testing under appropriate containment conditions and operating procedures

Confined testing under a more natural setting but under conditions that limit release into the environment

Large Scale releases in the environment to study epidemiological efficacy of the released mosquitoes

Along the process will be independent risk management procedures to identify any potential risks, allay any stake holder fears and identify specific mitigation measures should need be. Regulatory approval will also be sought for each phase

SETTING AFRICA'S AGENDA-Genome Editing

Genesis of Interest in Genome Editing- AU Members Countries- Outcome of COP-MOP 2018, in Sharm El-Sheikh, Egypt

Political will expressed through the need to harness Emerging technologies....Gene Drive and Genome Editing

- All 55 AU member states requested for trainings on Genome Editing, development of regulatory guidance tool

- Regional and continental approach is needed in ***developing a harmonized policy on genome editing***

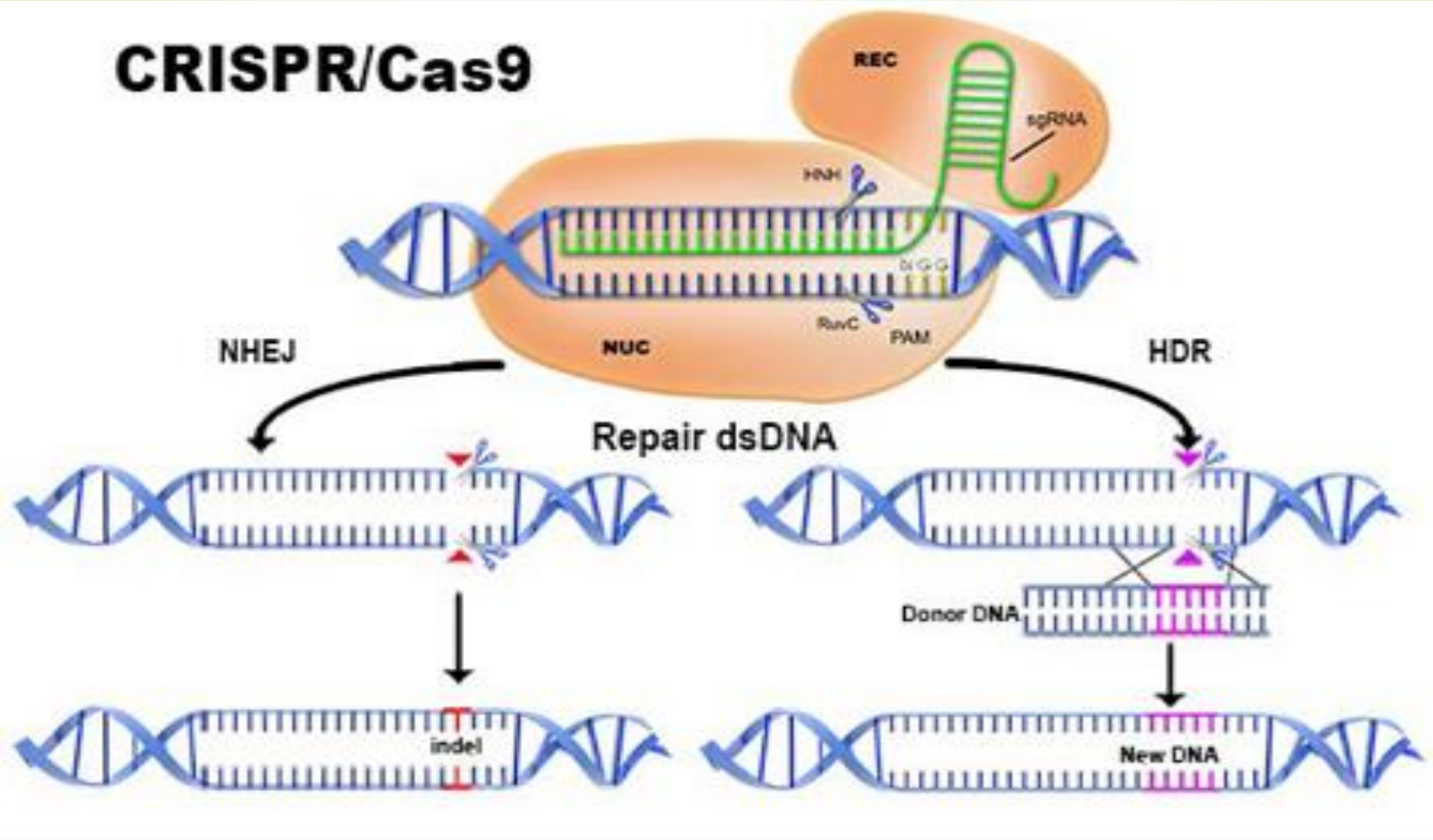
Training on Genome Editing and Constitution of the AU-Biosafety Regulators Forum (June 2019)

Genome Editing Technologies

Site Directed Nucleases (SDN)

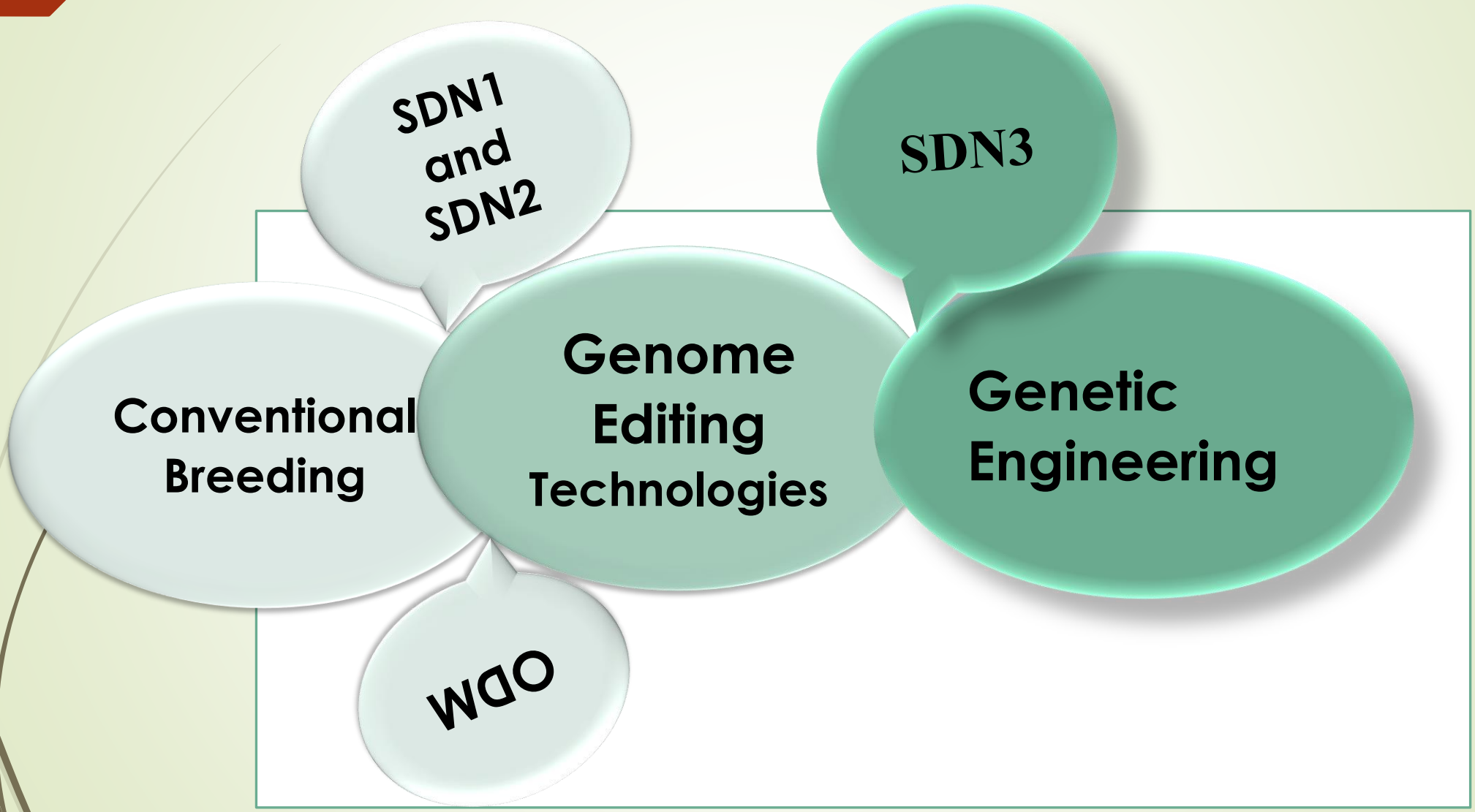
- Transcription- Activator Like-Effector Nucleases (TALENS)
- Zinc Finger Nucleases (ZFNs),
- Meganucleases or homing endonucleases
- CRISPR and Cas associated proteins,

Oligonucleotide DNA Mutagenesis (ODM)

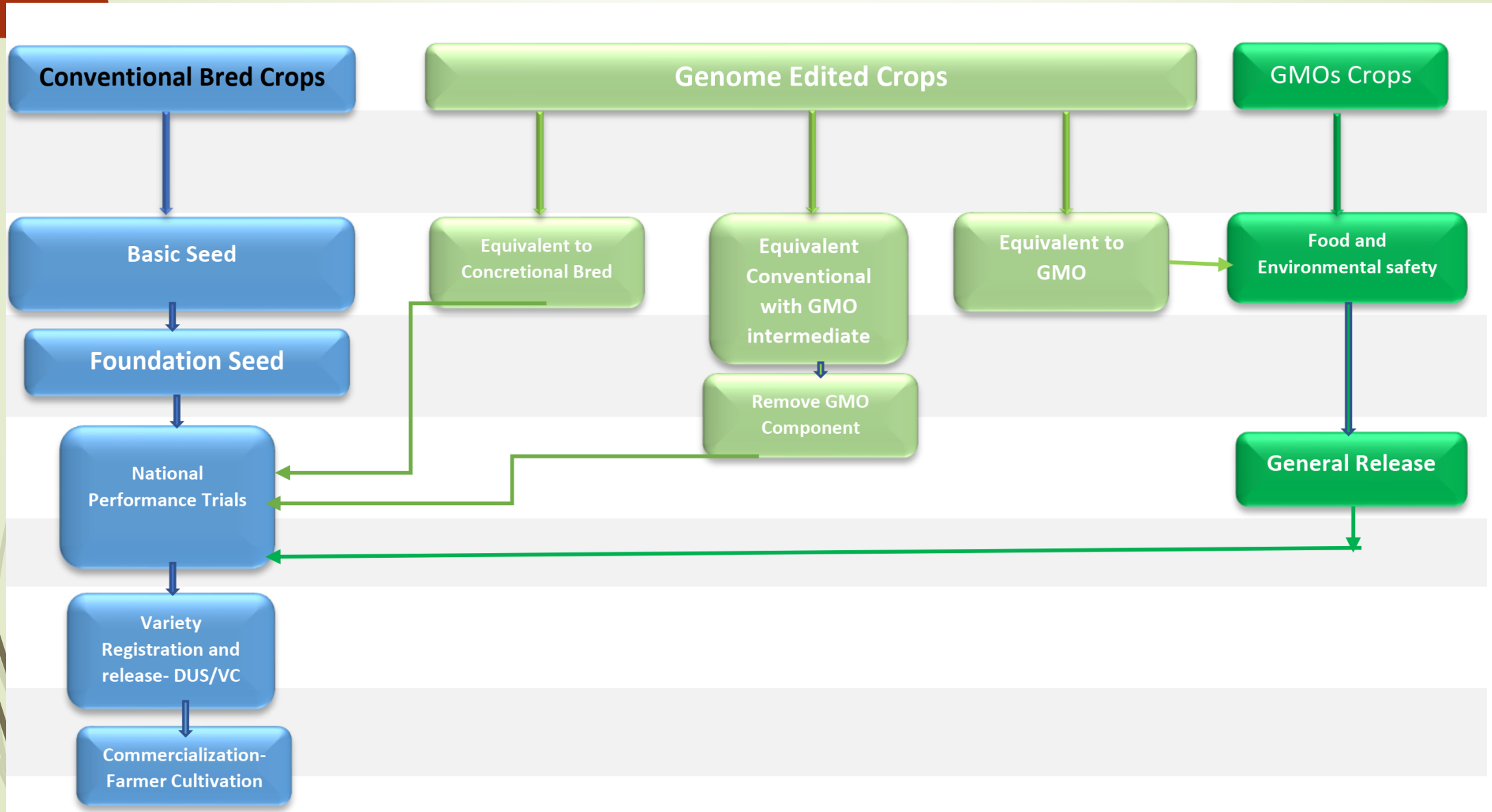


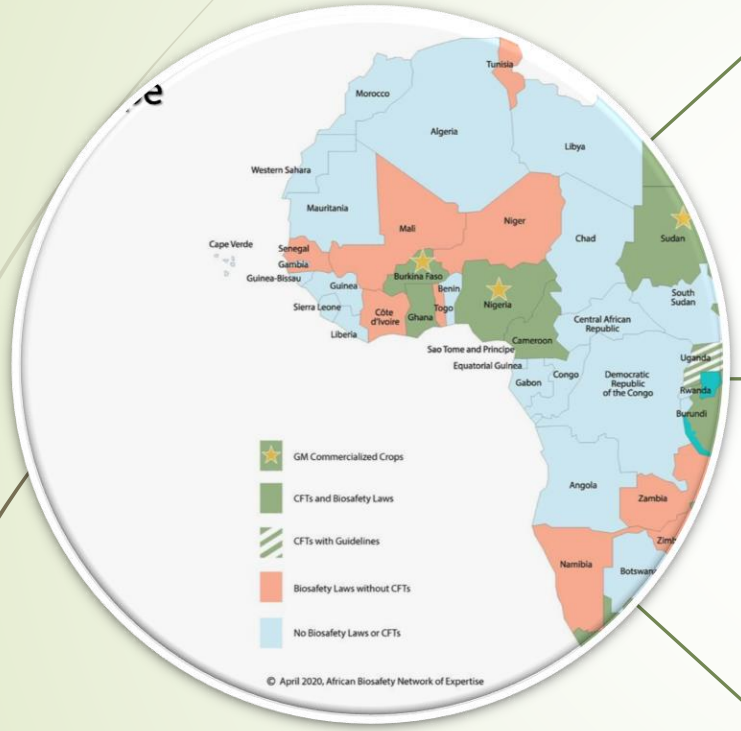
https://www.bing.com/images/search

Relationship in four Approaches



Regulatory Status of Conventional, Genome edited and GMOS crops





Nigeria

- Equivalent to Conventional breed crops
- Equivalent to convention Breed Crop but with GMO intermediate
- Equivalent to GMO crop
- Notification to NBMA

Kenya

- Equivalent to Conventional breed crops
- Equivalent to conventional Breed Crop but with GMO intermediate
- Equivalent to GMO crop
- Notification to NBA

Malawi
Ghana
Ethiopia
eSwatini
Burkina Faso

- Countries that organized Capacity Building in Science and regulation of Genome editing-
- Have Zero draft Guidelines

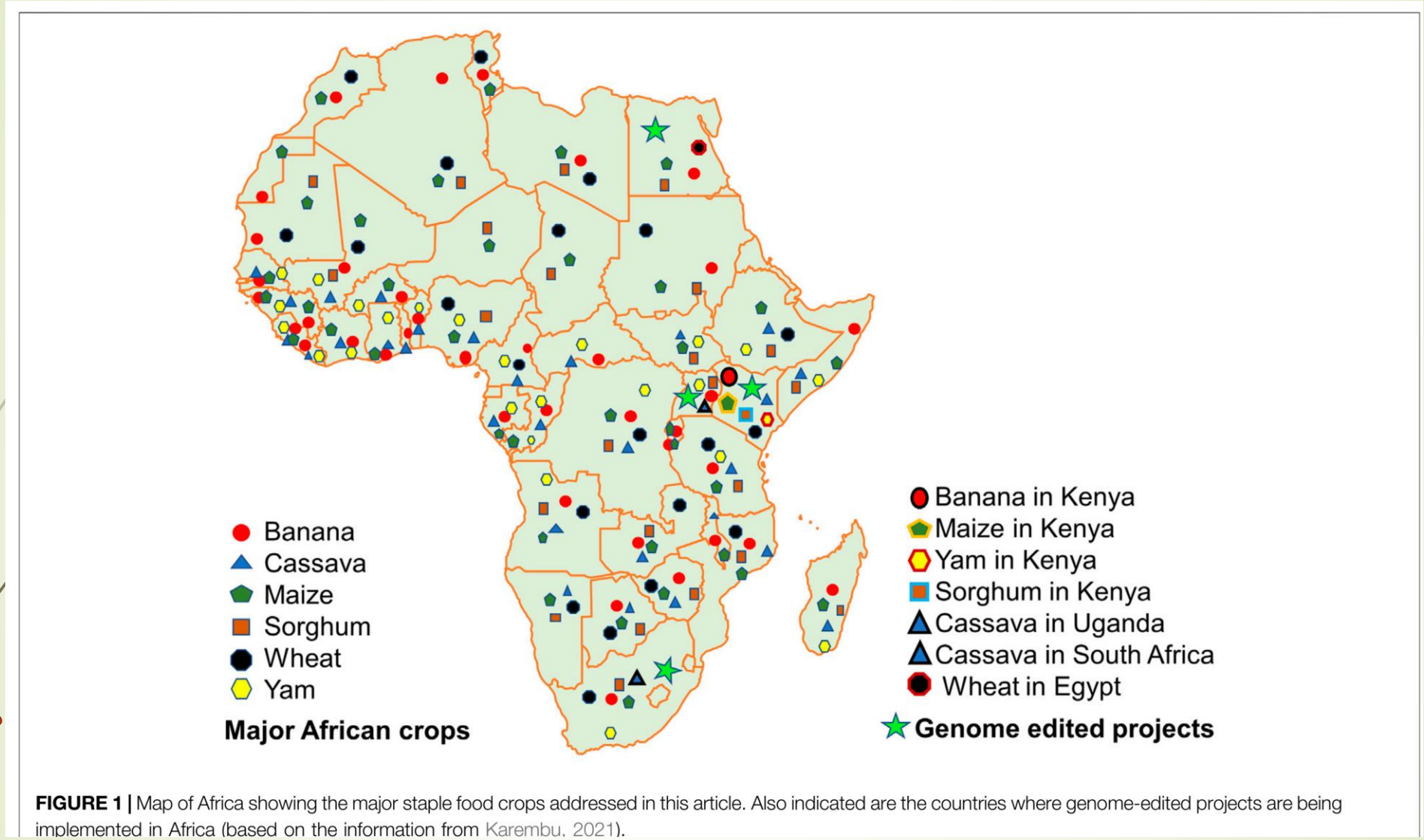


FIGURE 1 | Map of Africa showing the major staple food crops addressed in this article. Also indicated are the countries where genome-edited projects are being implemented in Africa (based on the information from Karembu, 2021).

Genome Editing in Africa- Source Tripathi et al, 2022

Genome Edited Rice Resistant to Bacterial Blight

Rice Resistant to Bacterial Blight. *G*enome edited (*SWEET11, SWEET13 SWEET14*) rice resistant to bacterial blight developed by the University of Missouri used *Agrobacterium tumefaciens* to introduce CRISPR-Cas gene editing reagents into rice cells.

No DNA repair template was provided, and conventional breeding was used to select progeny that contained the intended edits without the introduced exogenous DNA.

Recently, USDA-APHIS stated that this genome edited rice line is not regulated pursuant to 7 CFR part 340, because the rice is not a pest and no plant pest sequences were inserted in it.

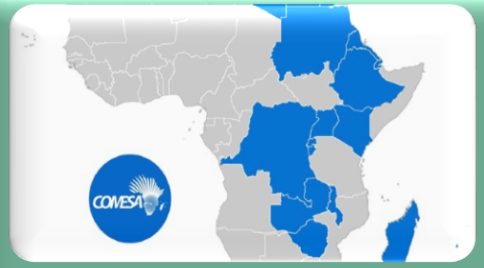
AUDA-NEPAD and ANB Visit To Bobo Dioulasso, Burkina Faso
Olalekan Akinbo and Moussa Savadogo

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

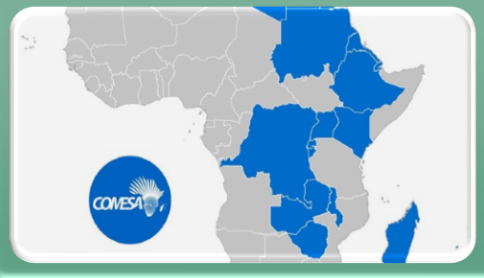
Role of Regional Economic Communities in harmonization

Role of Regional Economic Communities

ECOWAS. Currently, ECOWAS is drafting Regulation C/REG.5/05/08 on the adoption of an Action Plan for the Development of Biotechnology and Biosafety in the ECOWAS Region. Commercialize- **Nigeria, expect Ghana and Burkina Faso soon**



COMESA. In 2014, the Council of COMESA Ministers endorsed the implementation of the COMESA Biotechnology and Biosafety Policy, which translated into the COMESA Biotechnology and Biosafety Policy Implementation Plan.



COMESA. Thirteen COMESA countries have a biosafety regulatory system; **five of these countries (Ethiopia, Sudan, Kenya, Malawi, and Eswatini)** have commercialised GM Crops (ABNE, 2020). The efforts stalled and efforts to revive are ongoing

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

Role of Regional Economic Communities

SADC. Given the divergent views towards genetically modified organisms technology among SADC members states, harmonisation of GM regulation is posed to be more challenging.

In 2003 SADC, sub-regional level, guidelines were drafted and adopted, through the SADC Advisory Committee on Biotechnology and Biosafety. However, little or no progress towards implementation has been accomplished (Morris, 2014).

Despite this slow progress, **eSwatini, Malawi, Mozambique, South Africa**, have made giant strides towards GMOs technology. HTTPs://www.researchgate.net/publication/280740086_Biosafety_Regulatory_Systems_in_Africa

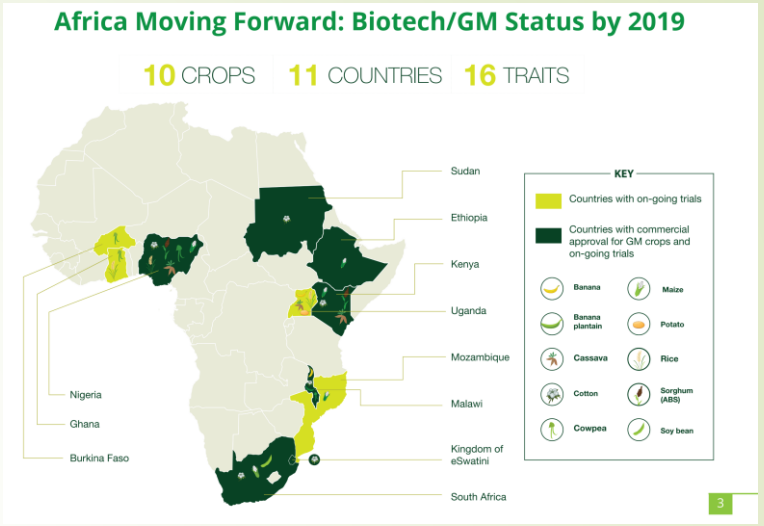
ON-GOING URGENT BIOSAFETY ISSUES AT INTERNATIONAL FORA

Post-2020 Global Biodiversity Framework- Geneva Meeting and Ongoing Nairobi Meeting. Areas of Concern- DSI, Synthetic Biology and Article

Synthetic Biology-

Open-ended Working Group on the Post-2020 Global Biodiversity Framework, third meeting virtually from 23 August to 3 September 2021, reports digital sequence information on genetic resources and undertook a text-based review of the first draft of the post-2020 global biodiversity framework..

Biosafety Laws in Africa



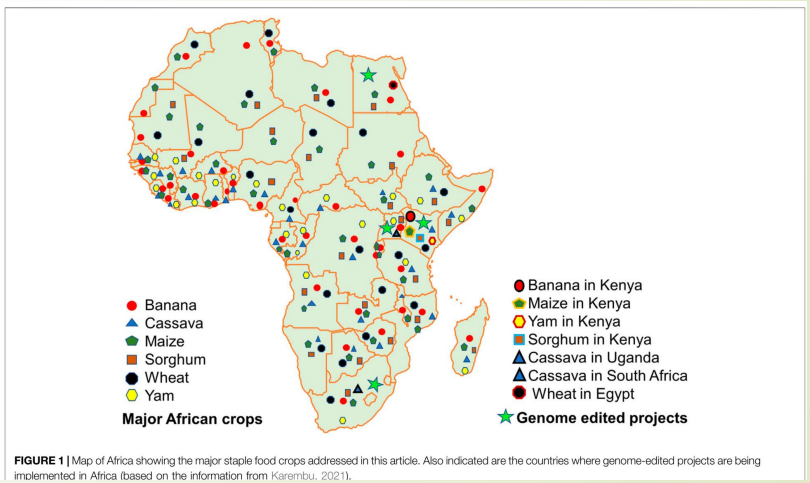


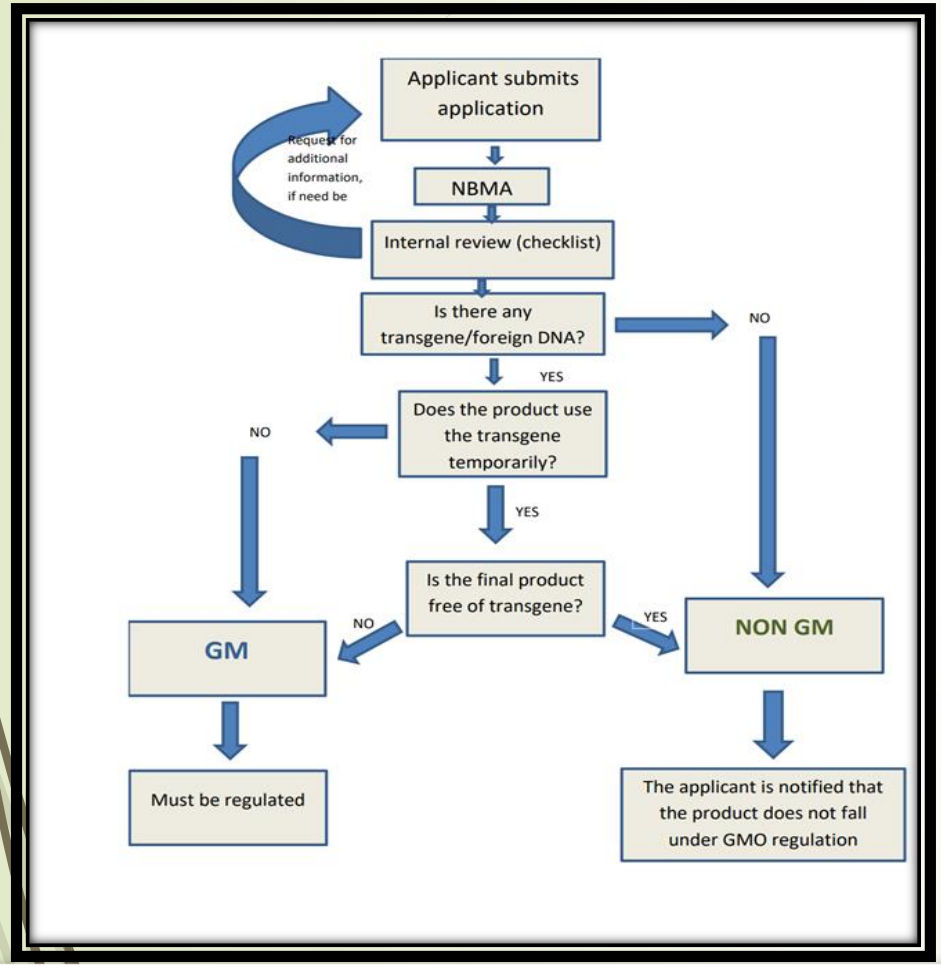
FIGURE 1 | Map of Africa showing the major staple food crops addressed in this article. Also indicated are the countries where genome-edited projects are being implemented in Africa (based on the information from Karembu, 2021).

Acknowledgments- Partners and Collaborators

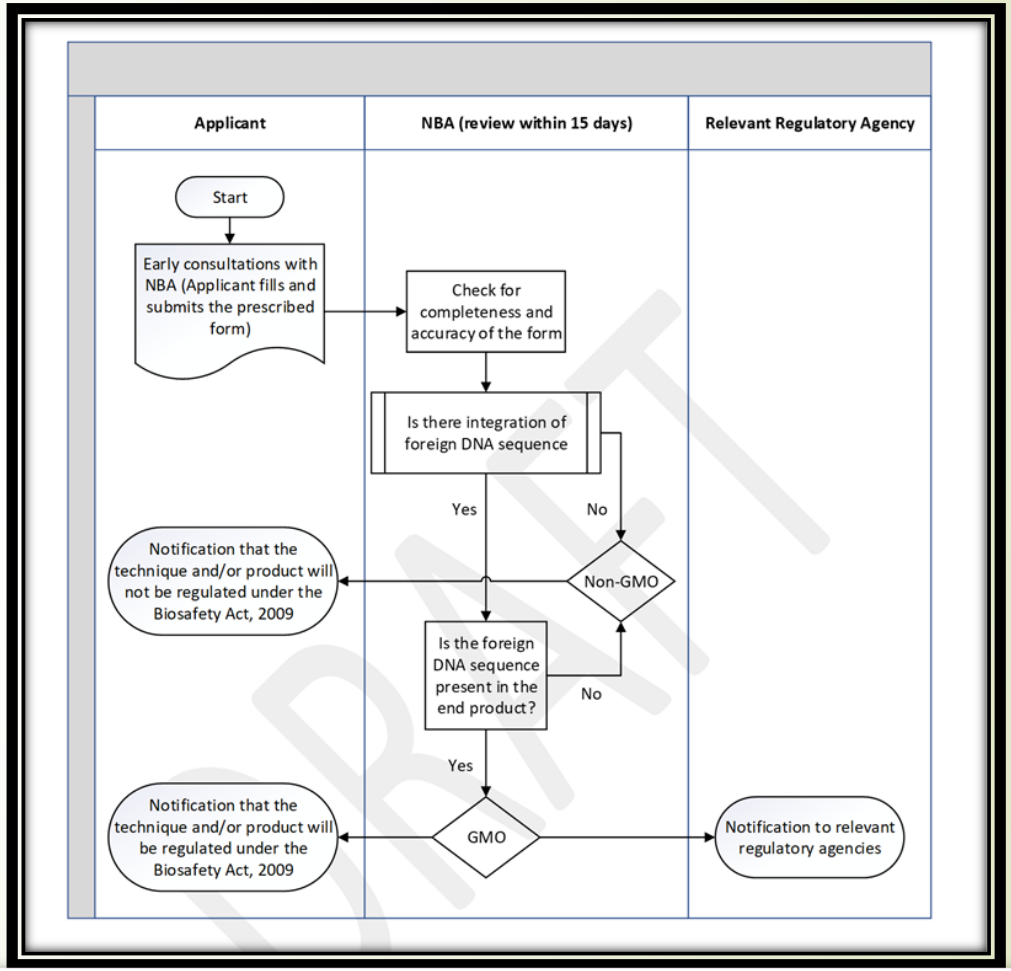
NATIONAL BIOSAFETY AUTHORITIES

OF AU MEMBERS COUNTRIES

Nigeria and Kenya Approaches to Regulation of Genome Editing



Source: www.nbma.gov.ng/our-guidelines



Source: KNBA National Biosafety Conference 2020

AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

First Malaria Vaccine to Combat Malaria

- Launch of the First Malaria Vaccines
- Africa Appreciates that some Africa countries are reporting zero malaria mortality- Cape Verde,
- The problem of Malaria the rest of 50 Africa Union Members countries is still severe and therefore the need of more tools including gene drives and the newly launched vaccines.

INTERNATIONAL NSTRUMENTS

- Convention on Biodiversity- three objectives
- Cartegena Protocol on Biosafety
- Liability and Redress Kualor Lumpur
- Access and Benefits Sharings