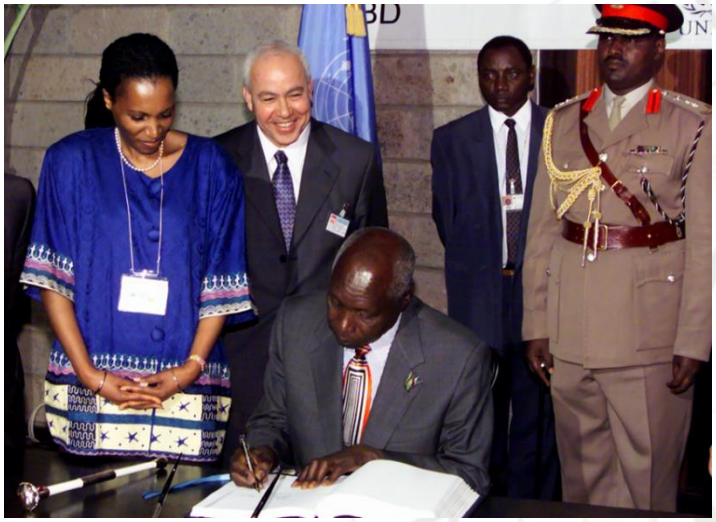
NATIONAL BIOSAFETY AUTHORITY
NACOSTI BUILDING (2ND FLOOR)
UPPER KABETE, OFF WAIYAKI WAY
P.O. Box 28251 – 00100, Nairobi. | Tel: +254 20 267 8667
Email: info@biosafetykenya.go.ke | Website: www.biosafetykenya.go.ke

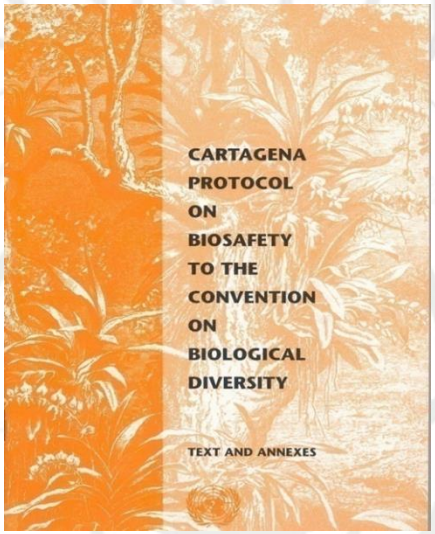
Kenya regulatory approaches to modern biotechnologies - GM and Genome Editing

Josphat Muchiri
Ag. Director, Biosafety Research & Compliance
National Biosafety Authority, Kenya
18th March 2025

SPS COMMITTEE THEMATIC SESSION ON INNOVATIVE REGULATORY APPROACHES TO FACILITATE SAFE TRADE

The Cartagena Protocol on Biosafety

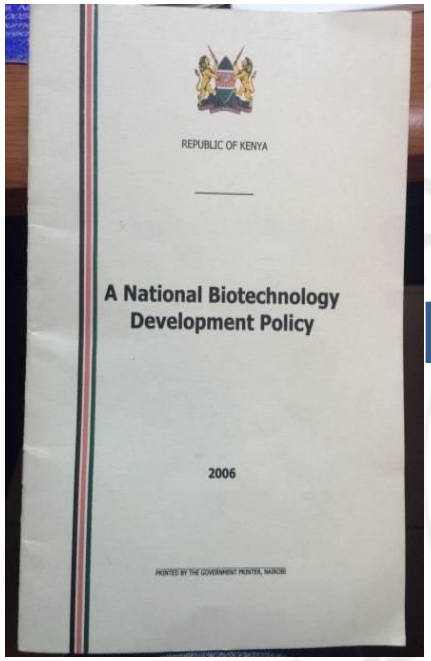


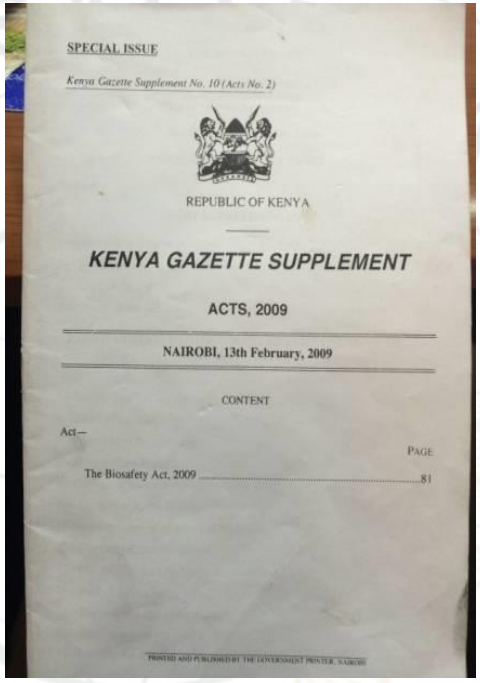


Convention on Biological Diversity

- Kenya signed/Ratified Cartagena Protocol on Biosafety - (2000 & 2003);
- Demonstration of Kenya's commitment to the global governance of modern biotechnology and biodiversity conservation;
- Aspiration to become a key participant in the global biotechnology enterprise (National Biotechnology Development Policy of 2006);

Kenya National Biosafety Framework





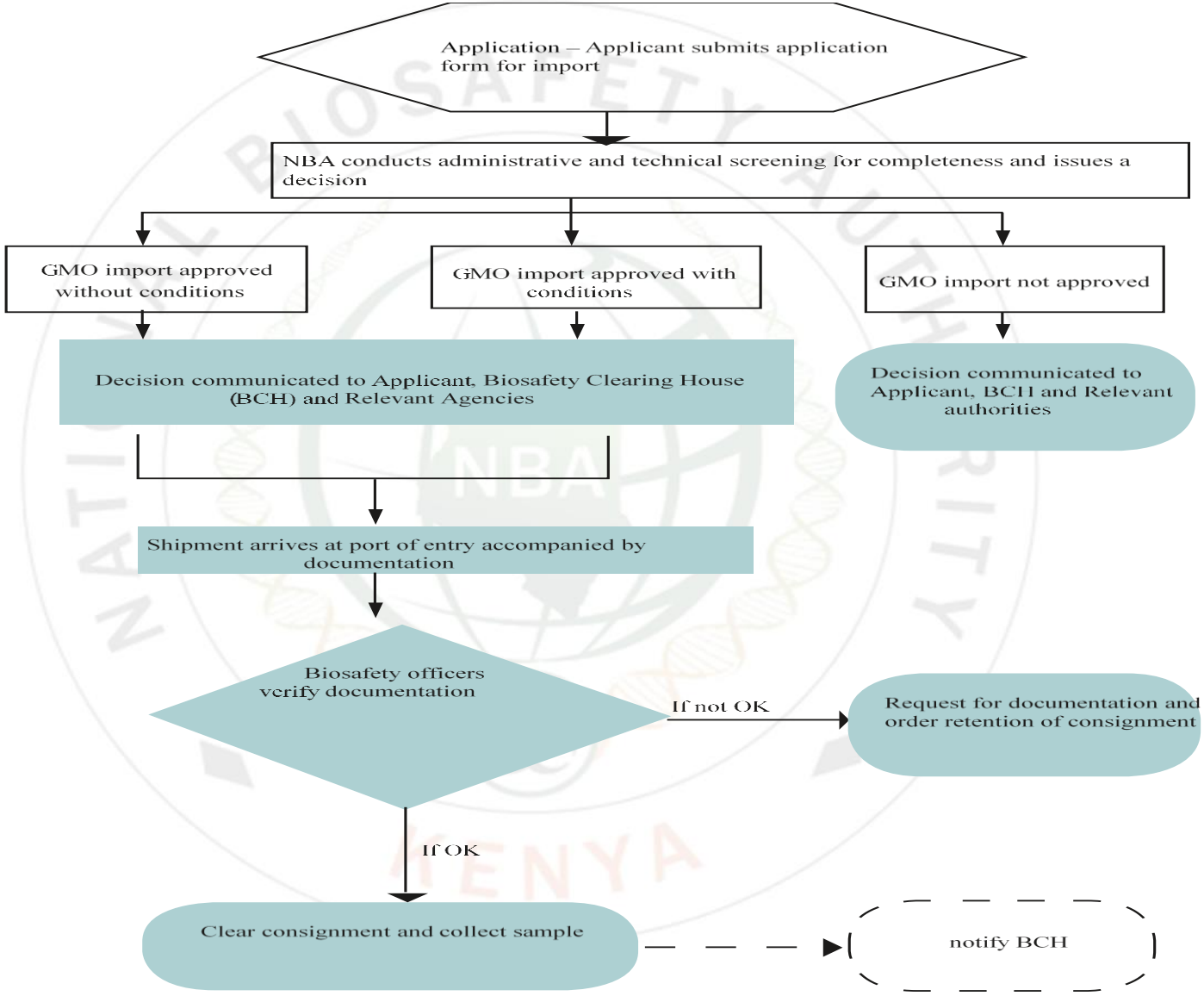
Biosafety Regulations:

1. The Biosafety (Contained Use) Regulations (2011)
2. The Biosafety (Export, Import and Transit) Regulation (2011)
3. The Biosafety (Environmental Release) Regulations (2011)
4. The Biosafety (Labeling) Regulations (2012)
5. National Guidelines on various areas eg Guidelines on Genome editing

GMO Applications Types

- Import, Export and Transit
- Contained use research (Lab, greenhouse and Field Trials)
- Environmental release and/or Placing on the Market

Procedure for Import of GM Products



Procedure for Environmental Release

Screening | **Technical Review** | **Decision Making**

Application

Fee: KSh. 850,000 ($6290)

NBA Secretariat

Completeness & Accuracy
Acknowledge: 30 days





SECs

RAs

Experts

NBA Secretariat

Public Submissions + SEC + RAs + Experts + Applicant = Consolidated Risk Assessment

NBA Board



Approve / Reject

Appeal

Monitoring

Summary of NBA Decisions on GMO Applications

Status	Contained use (Lab experiments)	Contained use (Confined field trials)	Import and transit (Decisions before the ban)	Environmental Release, placing on market
Approved	41	16	28	3
Rejected/withdrawn	0	0	2	1
Pending	1	0	1	2
Total	42	16	31	6

Approvals for Environmental release

1. **Bt cotton (MON 15985 BollGuard II)**– Commercialized in January 2020. Being cultivated in Eastern, Coast, Central, Western and Nyanza Regions.

2. **Bt maize (MON 810)-** 3 maize varieties approved for commercialization in January 2025, pending seed bulking and demonstration plots

3. **Virus Resistant Cassava (Cassava brown streak disease) (Event DPS 4046) –** Undergoing National Performance Trials by KEPHIS which are almost complete

Pending Applications for Environmental release

1. **Bt maize (MON 89034)-** Genetically modified for resistance to maize stem borers and fall army worms. *Completed public participation, currently undergoing risk assessment and socioeconomic impact assessment*

2. **Irish Potato–** Genetically modified for resistance to potato late blight disease. *Currently undergoing administrative screening*

Genome Editing Guidelines

- The Guidelines are designed to provide a technical guidance to applicants on the criteria for determining which genome editing organisms or their derived end products are regulated under the Biosafety Act, 2009.

- Key features of Kenya's Genome Editing Guidelines include:

  - An **early consultation stage** where the applicant fills out a simple form providing information/data that facilitate decision making;

  - Expeditious timelines (30- 90 days) for decision making at the early consultation stage;

  - Clear flow of steps on consideration of the various options on the basis of information/data provided;

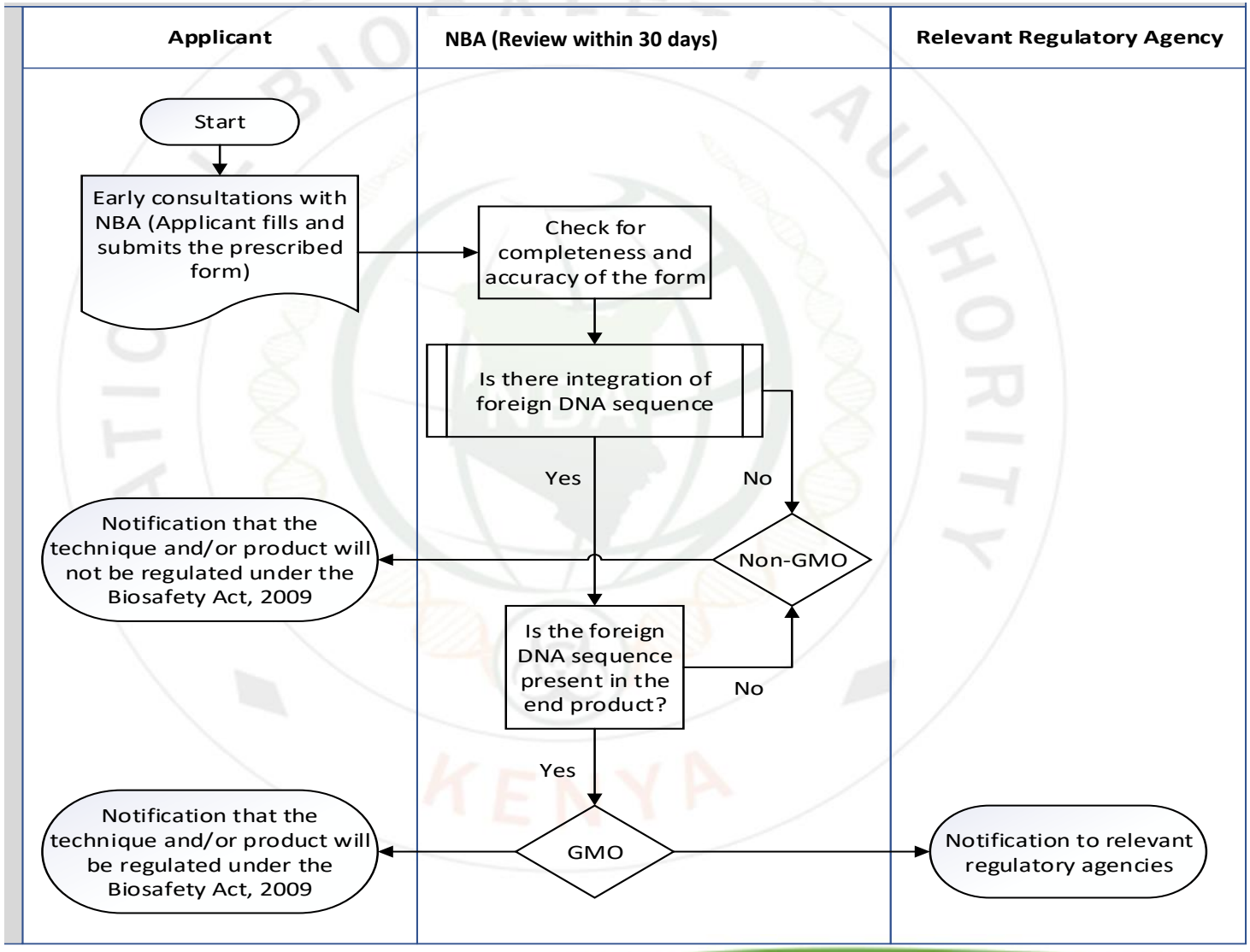
Objective of the Guidelines

To provide a technical guidance to applicants & reviewers on the criteria for determining which genome editing techniques and/or derived end products are regulated under the Biosafety Act, 2009.

Decision Making Process

- Any genome editing activity (research or commercial) will require clearance/approval from NBA
- Fill and submit Early Consultation Form (available on NBA website)
- Payment of relevant application fees
- Review& Decision: **30 to 90 days**

Flow Chart for Determination of Regulatory Approach for Genome Editing



Gene edited Research Projects Regulated as GMOs- Having novel/foreign genes

1. African swine fever Vaccine
2. Trypanosome resistance goat
3. Genome Edited Grass Pea
4. Genome edited Sorghum (anthracnose resistance)
5. GE Yam (Vitamin A and Diseases resistance)
6. GE cassava (Nutritional enhancement)
7. Banana Resistance to viruses and aphids
8. Cassava for early flowering
9. Banana (fungal and bacterial resistance)
10. Potato for Potato Virus Y resistance
11. Gene edited chicken

Genome edited Projects exempted from GMO Regulation- Having no novel/foreign genes

1. Gene edited maize lines with resistance to Maize Lethal Necrosis (MLN)- KALRO
2. Gene edited nitrogen fixing bacteria used as a seed treatment for cereal crops- Pivot Bio
3. Gene edited sorghum lines with resistance to striga- Kenyatta University (KU)
4. Gene edited sorghum lines with herbicide tolerance- KU
5. Genome edited rice lines with resistance to Bacterial leaf blight- KALRO

Addressing Gaps in the Legal Framework

- Current Biosafety Act addresses GMOs, equivalent to the Cartagena Protocol LMO

- The B/Act is not explicit on derived products of GMOs, and is also silent on emerging Biotechnologies,

- Kenya is currently re-looking at the Biosafety Act to provide for Regulation of Derived Products of GMOs, Emerging technologies such as Genome editing, Gene drives and Synthetic Biology. Regulations for GMO and the other Guidelines will however be different

Thank You

For more information:

Website: www.biosafetykenya.go.ke

E-mail: info@biosafetykenya.go.ke