NATIONAL BIOSAFETY AUTHORITY
COMMISSION FOR HIGHER EDUCATION CAMPUS
REDHILL ROAD, OFF LIMURU ROAD

P. O. Box 28251 – 00100, Nairobi. | Tel: +254 20 267 8667
Email: info@biosafetykenya.go.ke | Website: www.biosafetykenya.go.ke

Environmental safety aspects of regulations for GM Animals in Kenya

Prof. Dorington Ogoyi
Chief Executive Officer, NBA, Kenya

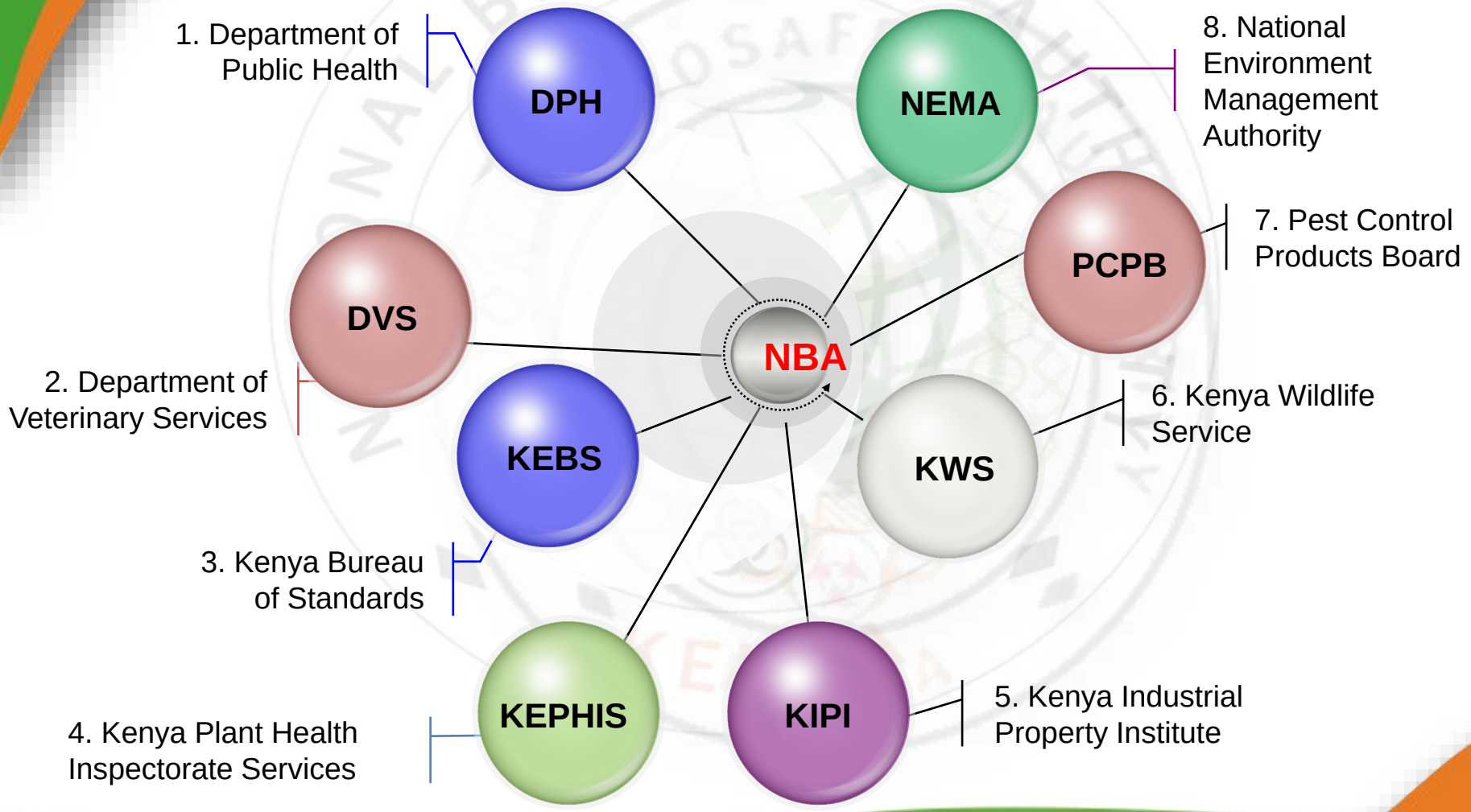
Virtual Workshop on Animal Biotechnology

7th October, 2020

Vision and Mission

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

Regulatory Agencies (RAs)



Vision: A world-class Biosafety Agency

Biosafety Regulations

- Four regulations have been gazetted for implementation of the Biosafety Act:
  - **Contained Use**
  - **Environmental Release**
  - **Import, Export and Transit**
  - **Labeling**
- Under these regulations, a number of guidelines have been developed to offer more clarity
- These guidelines serve as implementing tools for Biosafety (Contained Use) regulations, 2011, for regulation of GM animals under containment and confinement in Kenya

Guidelines for regulation of genetically modified animals under containment and confinement in Kenya

Objective, Scope and Exemptions

Objective

- To offer guidance guidance to researchers and developers working with GM animals as pertains legislative requirements and compliance aspects that apply to animals

Scope

- These guidelines shall apply to any activity involving GM animals undertaken within a facility, installation or other physical structure controlled by specific measures

Exemptions

- Products which are pharmaceuticals for human use
- GM animals previously approved for environmental release

Information to be submitted by the Applicant includes:

- Information regarding the GM or intended GM animal
- Project personnel qualifications/ proof of compliance training
- Contingency plans and emergency measures
- Risk Analysis - risk assessment, risk management and risk communication
- Containment and Confinement measures for the GM Animals
  - Laboratory facilities
  - Confined field trial sites
  - Transportation and Storage
  - Disposal plan of GM animals and their products

Some risk assessment considerations for GM animals

- GM animal impacts on human and animal health: through ingestion or other routes of exposure
- Fitness advantage or disadvantage
- Gene transfer to other species
- GM animal interaction with target organisms, where applicable
- GM animal and non-target organisms' interactions
- GM animal impact on biogeochemical processes: through incorporation of dead GM animals into soil and water systems

Summary of Decision Making Process

Processing GMO Application for Environmental Release

Screening

Technical Review

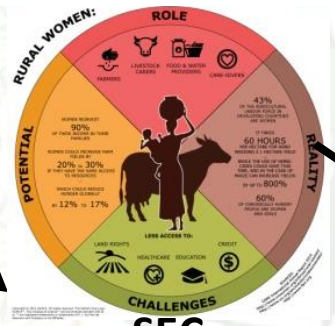
Decision Making

Application

NBA Secretariat

Completeness & Accuracy
Acknowledge: 30 days

Public Consultation



SEC

RAs

Expert Reviewer

NBA Secretariat

NBA Board

Decision:
90-150 days
Approve / Reject

- **Consolidated Risk Assessment (food & environment)**
  (RAs, Experts & Applicant)
- **Submissions by Public**
- **Socio-Economic Considerations**

Decision Making

- NBA Board makes decisions on GMO Applications based on;
  - Information submitted by applicant
  - Reports from Expert Reviewers
  - Information & conditions submitted by relevant RAs
  - Risk Assessment Report
  - Relevant submissions by members of public
  - Socioeconomic considerations arising from impact of GMOs to the environment

Approval

- The Authority shall make and communicate the final decision within 150 days of receipt of an application but not earlier than 90 days
- Approval shall be valid for 5 years with a possibility for renewal for contained use/confined
- For Environmental release approval is for initial period of 10 years, renewable for a further 10 years then deregulated.

Inspection / Monitoring and Reporting

Inspection and Monitoring

- Inspection of the proposed trial site shall be done before commencement of the project and annually during the course of the project
- Monitoring will be done by the Authority in partnership with the relevant regulatory agencies.

Reporting

- The applicant shall be required to submit reports, on a quarterly and annual basis, on the progress of the activity during the project's approval period

9th Annual Biosafety Conference, 10-13th November 2020

Pre-Conference Session: 10-11th November 2020 focusing on Genome Editing Technology Applications and Regulations

Main Conference: 12-13th November 2020. Theme; **"Functional Biosafety Systems towards Commercialization of Agricultural Biotechnologies for Economic Development in Kenya**

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THANK YOU

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