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

Current status of the Environmental and Contained Use regulations on GM animals in Kenya

Prof. Dorington Ogoyi
The 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

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

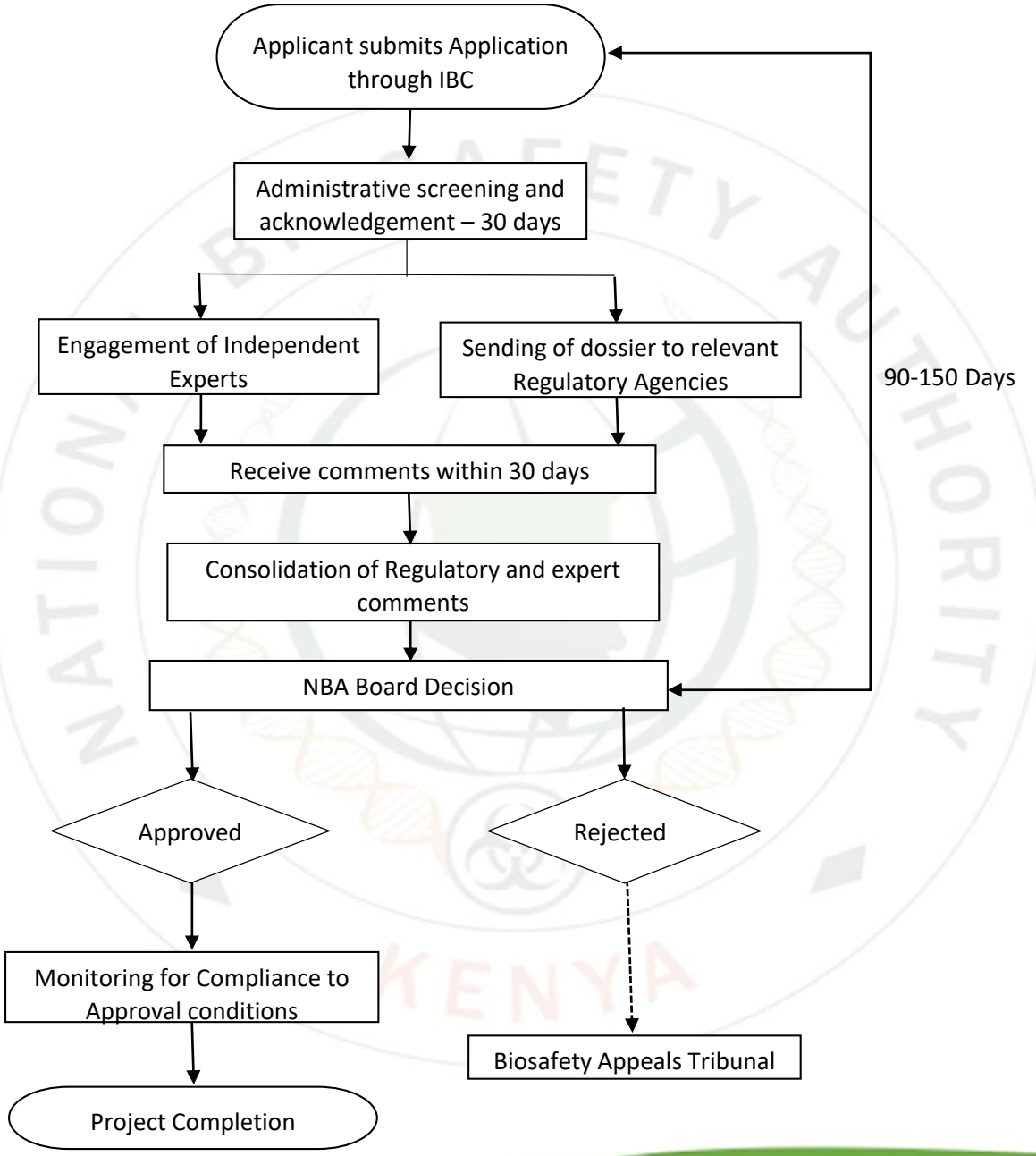
Exemptions

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

Regulatory framework

- The Authority has a coordinated framework which outlines the working with other government and regulatory agencies
- The Authority shall work with Institutional Biosafety Committee (IBCs) in liaison with Institutional Animal Care and Use Committees (IACUCs) on matters concerning animal welfare
- The proponent shall conduct risk assessment which shall be revised by the IBC before sending to the NBA

Application process
Using the appropriate application form, through an IBC


Applicant submits Application through IBC
Administrative screening and acknowledgement – 30 days
Engagement of Independent Experts
Sending of dossier to relevant Regulatory Agencies
90-150 Days
Receive comments within 30 days
Consolidation of Regulatory and expert comments
NBA Board Decision
Approved
Rejected
Monitoring for Compliance to Approval conditions
Biosafety Appeals Tribunal
Project Completion

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

Containment and Confinement measures for GM Animals

- General requirements for containment of different classes of GM animals have been outlined in compliance with Biosafety (Contained Use) Regulations, 2011
- These include:
  - Animal units for large animals e.g. cows, horses, donkeys, pigs, sheep, goats, etc
  - Animal units for small animals e.g. mice, guinea pigs, rabbits, etc
  - Containment for aquatic animals - for example, fish
  - Containment units for birds e.g. poultry, turkeys, ducks, etc
  - Containment units for GM invertebrates e.g. mosquitoes, fruit flies, silk worm, etc

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

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

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

THANK YOU

Web: www.biosafetykenya.go.ke