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Guidelines for regulation of GM animals under containment and confinement in Kenya

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The Biosafety Act, 2009

The law that established the NBA and provides the legal framework for her mandate to regulate all activities involving GMOs in food, feed, research, industry, trade and environmental release in Kenya

Biosafety Regulations

Developed as implementing tools for the Biosafety Act, 2009 to lay clear procedures on handling GMOs, whether plants, animals or microorganisms, at different phases of development

Biosafety (Contained Use) Regulations, 2011

Context and Scope

- Cover activities involving GMOs under research. (**Lab, Green house, Screen houses, Animal units, CFT**)

Objective (Art. 3)

- To ensure that potential adverse effects of GMOs in research are addressed to protect human health and the environment when conducting contained use.

Biosafety (Import, Export & Transit) Regulations, 2011

Context and Scope

- Cover activities involving importation into, exportation out of and movement of GMOs through Kenya

Objective (Art. 3)

- To ensure safe movement of GMOs into and out of Kenya while protecting human health and the environment

Biosafety (Environmental Release) Regulations, 2011

Context and Scope

- Cover activities involving release of GMOs into environment; and placing on market

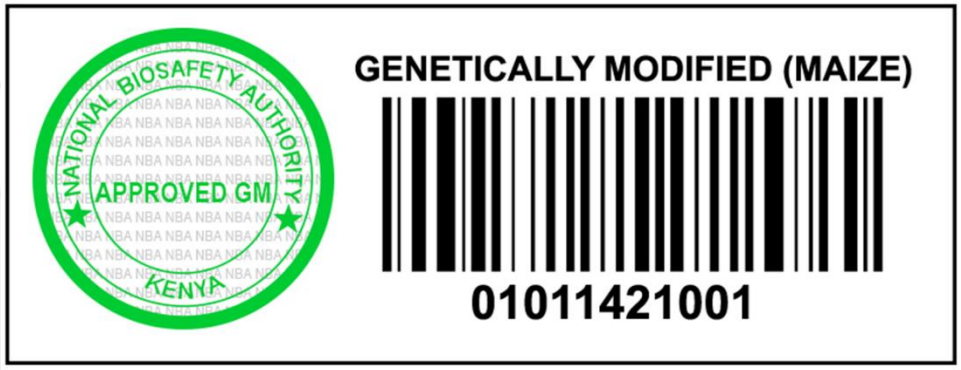
Objective (Art. 3)

- To ensure that potential adverse effects of GMOs are addressed to protect human health and the environment when conducting environmental release.

The Biosafety (Labeling) Regulations, 2012

Context and Scope

- Cover GMO products approved for the market



Objective (Art. 3)

- For consumer information
  - GMO, any significant differences in composition, nutrients, anti-nutrients, allergens, uses, ethical/ cultural/ religious
- To facilitate traceability of GMO products

Other Enabling Tools

- Guidelines
- Manuals
- Standard Operations Procedures (**SOPs**)

Examples:

- Guidelines for Food/feed safety assessment
- Guidelines for Environmental Risk Assessment
- Guidance documents on Monitoring and Inspection of approved projects
- Guidelines for general surveillance, sampling and GMO testing
- **Guidelines for determining the regulatory process of genome edited organisms and products in Kenya**
- **Guidelines for regulation of genetically modified animals under containment and confinement in Kenya**
- *Etc*

Guidelines on Regulation of genetically modified animals under containment and confinement in Kenya

Scope & Objective

The guidelines serve as implementing tools for Biosafety (Contained Use) regulations, 2011:

- To offer guidance and clarity as pertains to considerations that apply to GM animals under containment and confinement

Exemptions

- Products which are pharmaceuticals for human use
- Conventional breeding techniques as provided for in the Biosafety Act

Information to be Submitted

- Description of the unmodified animal
- The introduced gene, its source & function
- Description of the genetic modification method
- Molecular description of the GM animal providing details such as:
  - Phenotypic characteristics of the modified animal
  - Novel pathological, ecological and physiological traits in the GM animal:
    - Any known toxins produced by the animal including natural defense compounds
    - Any known allergens that emanate from these animals including natural defense compounds
- Methodology for detection of gene in the host organism or products.

Information to be Submitted

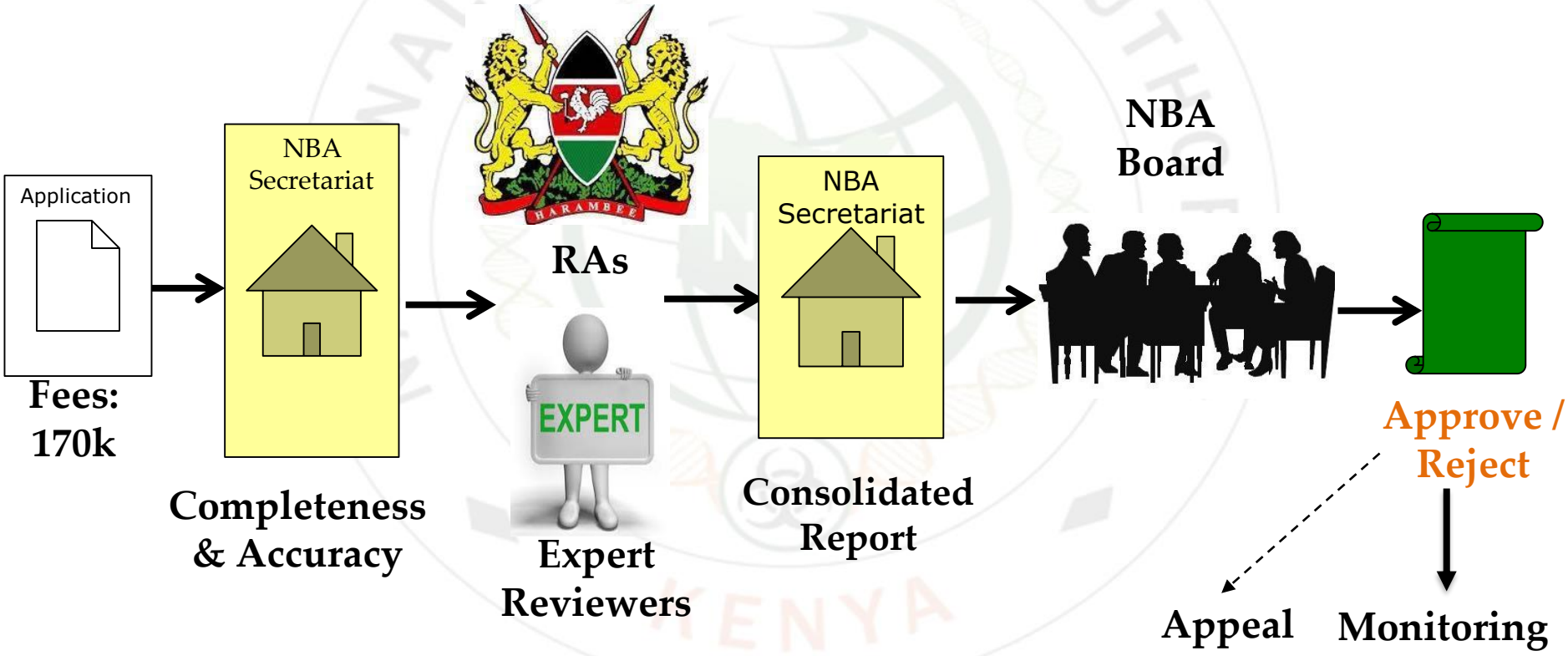
- Project personnel information (incl. qualification & training)
- Contingency plans and emergency measures
- Risk Analysis of GM animal (risk assessment, risk management and risk communication)
- Risk assessment:
  - Comparison between GM animal and its non-GM comparator focusing on determination of similarities and differences.
  - If a new or altered hazard, environmental or other safety concern is identified then;
  - Risk characterization to determine its relevance to human or/and animal health and the environment.

Risk Assessment Considerations

- 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 interaction with non-target organisms
- GM animal impact on biogeochemical processes: through incorporation of dead GM animals into soil and water ecosystems
- Risk management strategies proportionate to the risk identified

Approval Process for Contained Use Applications

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



- Decision in 90-150 days
- Approval is for 5 years

Containment & Confinement measures

- As stipulated in Part II-A of the Biosafety (Contained Use) Regulations, 2011 & as highlighted in Annex II of the guidelines
  - Laboratory facilities
  - Confinement facilities
  - Transport
  - Tagging and Labeling
  - Storage
  - Disposal of GM animals and their products
- Inspection and Monitoring

Conclusion

- For research phase, there's no discrepancy in NBA's regulation of GM animals as compared to GM plants, except in consideration of the facts that:
  - Animals move and plants cannot: containment & confinement
  - Animals require special transportation
  - 'Storage' of animals would differ from plants, and from one species to the next
  - There are special considerations due to animal welfare concerns that do not apply to plants
- As of now Kenya does not have guidelines for environmental release of GM animals

Guidelines on Regulation of Genome Editing Techniques in Kenya

Objective of the Guidelines

- In the absence of any substantive law on Genome editing, 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 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;
  - Categorization of Genome Editing outcomes expected to be regulated under the Biosafety Act 2009

Rationale

- Some genome editing techniques may lead to **products similar to GMOs**; while others may lead to **products similar conventional breeding**.

Scope

The guidelines apply to genome edited;

- Plants;
- Animals;
- Microorganisms

Exemptions

- Genome edited pharmaceuticals for human use
- Conventional breeding techniques as provided for in the Biosafety Act

Regulatory Considerations for GEd

Category 1: Regulated under the Biosafety Act

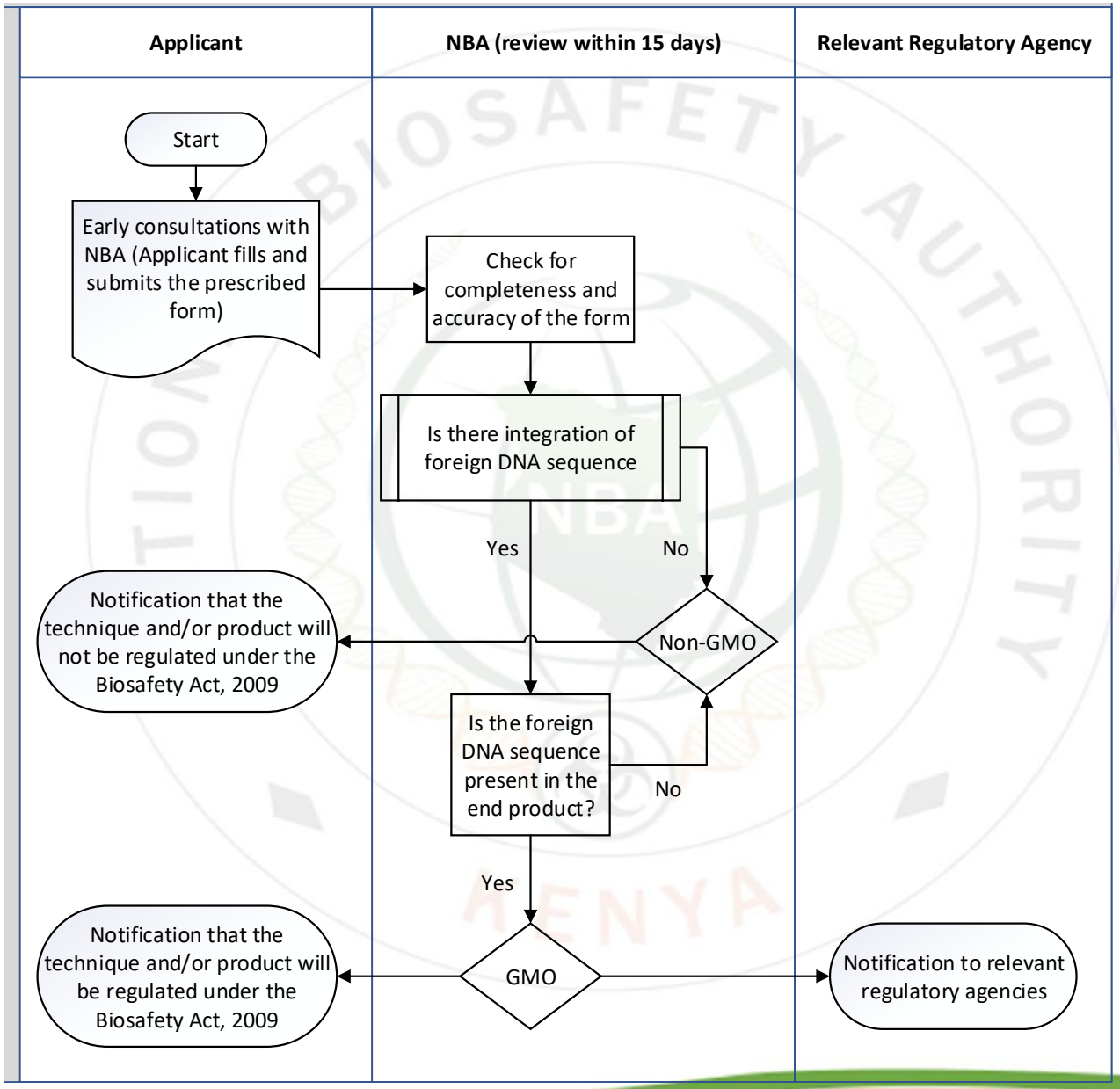
- All insertions of foreign genes and/or regulatory elements from non-sexually compatible species
- All instances where foreign DNA sequence (s) are detectable
- All instances where markers used (selectable and reporter genes) are present in the end product
- All cases where required data is not available
- Where research/ developmental phase starts with a GMO, regulation will be up to the stage where GMO component is removed/ segregated out

Regulatory Considerations for GEd

Category 2: NOT Regulated under the Biosafety Act

- All insertions using genes and regulatory elements from sexually compatible species
- All deletions/ knock outs provided there's no insertion of foreign genetic material
- Processed products whose inserted foreign genetic material cannot be detected
- Conventional breeding methods, mutagenesis, polyploidy and haploidy

Flowchart for the Early Consultation on Genome Editing



Decisions on Genome Editing Applications

- **Category One:** A determination by NBA that the genome edited organism or product has foreign genetic material
  - ✓Applicant is guided to make a full application that follows a full risk assessment and biosafety approval process.
- **Category Two:** A determination by NBA that the genome edited organism or product has no foreign genetic material
  - ✓Applicant is informed that the application is exempt from regulation as a GMO.

Provision for Review of the Guidelines

- The Genome editing Guidelines may be reviewed based on new scientific information.

- NBA also reserves the right to alter its decision if new scientific information previously unknown becomes available.

Decisions taken on GE Applications

Ten (10) Genome Editing applications at **research level** have been approved using the Biosafety Act 2009;

1. African Swine Fever Vaccine;
2. Goat for Trypanosome resistance;
3. Surrogate host chicken;
4. Sorghum for Striga resistance;
5. Sorghum (anthracnose resistance);
6. Yam (Vitamin A and Diseases resistance)
7. Cassava for Nutritional enhancement;
8. Banana for nano and caulimo viruses + aphids resistance;
9. Cassava for early flowering;
10. Banana for fungal and bacterial resistance;
11. Potato for Potato Virus Y resistance;

Applications for Trials

- Two Genome Editing applications to conduct Trials are have been received for early consultation:
  1. Maize resistant to Maize Lethal Necrosis (MLN) disease;
  2. *Kosakonia sacchari* and *Klebsiella variicola* bacteria species with enhanced nitrogen fixing capabilities;
     - *K. sacchari* associates with sugar cane crop and therefore has potential to associate with maize (Graminae)

Category Two Decision was Made last week

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