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Regulation of Genome Editing in Kenya

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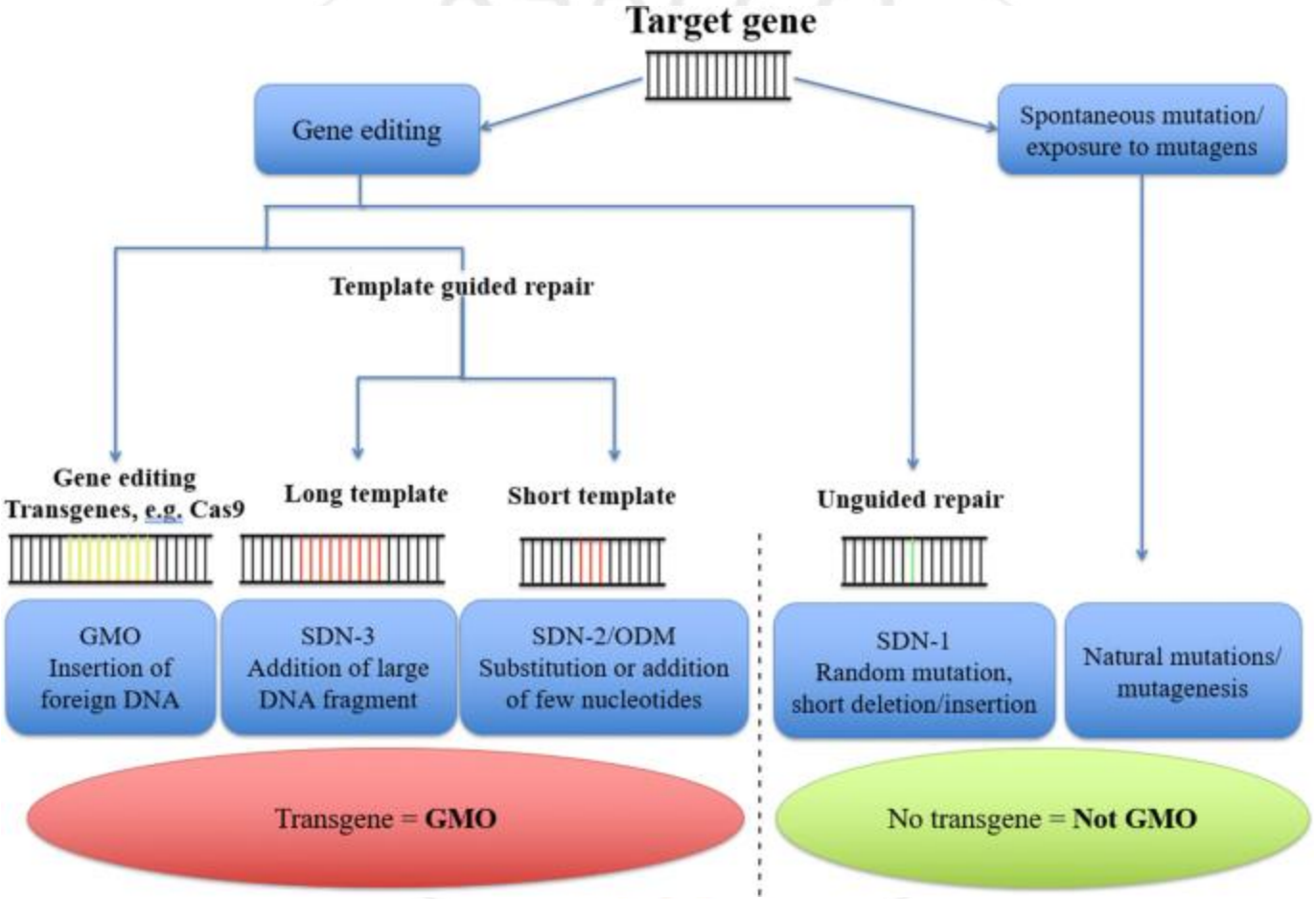
Genome Editing: Background



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 have also been made quite;
  - 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;
- Same approach taken by a number of other countries;

Decisions taken on GE Applications

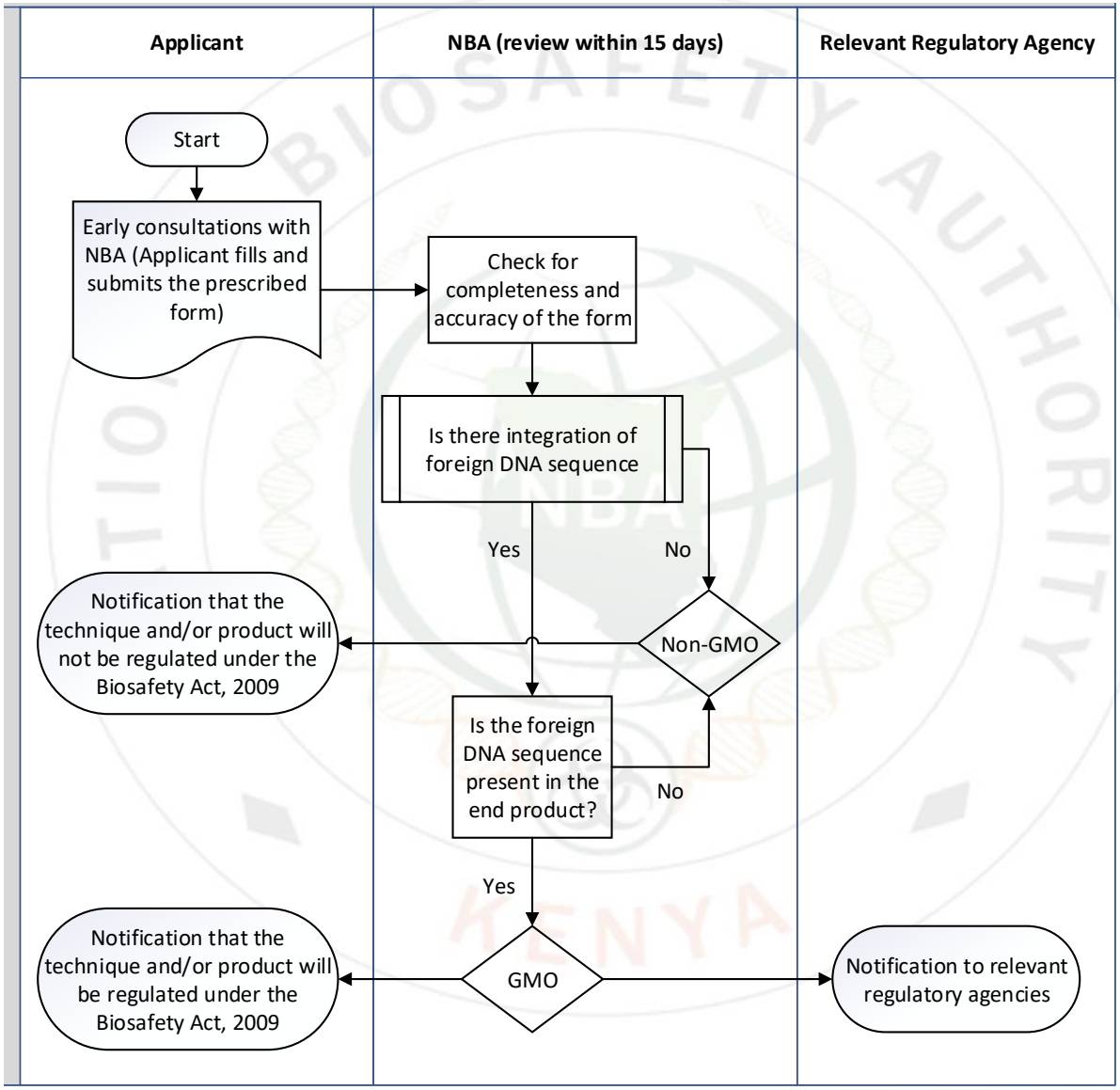
Eleven (11) Genome Editing applications at **research level** have been approved using the Biosafety Act 2009;

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

Scope

- The guidelines applies to;
  1. Genome edited plants;
  2. Genome edited animals;
  3. Genome edited microorganisms;
- Exemptions
  - The guidelines are not applicable to Genome edited pharmaceuticals for human use- *these are regulated by Pharmacy & Poisons Board*

Flowchart for the Early Consultation on Genome Editing



Possible Decisions on Genome Editing Applications

A) Scenario One: A determination by NBA that the genome edited organism or product has no foreign genetic material – ***Applicant is informed that he is exempt from regulation as a GMO.***

B) Scenario Two: 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.***

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.

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