



**Guidelines for Genome Editing in
Kenya**

Ref: NBA/TEC/ML/11

Revision No: 01

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NATIONAL BIOSAFETY AUTHORITY

GUIDELINES FOR GENOME EDITING IN KENYA

JANUARY 2025



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FOREWORD

Genome editing technology has been identified as a potential new option to augment existing interventions in pursuance of achieving the African Union Agenda 2063 and it is expected that proposed applications for genome editing technology for basic research, conservation, agriculture, public health and other purposes will likely continue to expand as genome editing tools become more refined.

Genome editing has broad applications in plant and animal improvement, as well as in the medical field. For example Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) has been used to edit the genome of rice resulting to improvements in yield-related traits, such as dense and upright panicles and reduced plant height; development of late flowering soybean, resulting in increased vegetative size; development of citrus plants resistant to citrus canker; generation of animals suitable for human disease modelling such as CRISPR-edited cynomolgus monkeys for brain disorders that cannot be fully studied in mice; studies for the treatment of Human Immunodeficiency Virus (HIV) among other applications.

In responding to the continuous advancement in genome editing technology, the Authority has developed a guideline document for determining the regulatory process of genome editing techniques through broad stakeholder consultations and review of regulatory mechanisms in other countries where such technology has been deployed.

The document incorporates the aspects of implementation, as well as essential testing pathways and implementation strategies in the country, taking into consideration all the possible socio-cultural and ethical issues. This document is not meant to detail how risk assessment and risk management of genome edited products will be conducted.



NEHEMIAH K. NGETICH
AG. CHIEF EXECUTIVE OFFICER
NATIONAL BIOSAFETY AUTHORITY



ABBREVIATIONS

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CPB	- Cartagena Protocol on Biosafety
CRISPR	-Clustered Regularly Interspaced Short Palindromic Repeats
DSBs	double-strand breaks
DNA	- Deoxyribonucleic acid
GE	- Genetically engineered
GM	- Genetically modified
GMO	- Genetically modified organisms
ODM	- Oligonucleotide-Directed Mutagenesis
r-DNA	- Recombinant-DNA
RNA	- Ribonucleic acid
SDN	- Site –Directed Nucleases
SNPs	single nucleotide polymorphisms
TALENs	- Transcriptional Activator Like Effector Nucleases
ZFNs	- Zinc Finger Nucleases



DEFINITION OF TERMS

Applicant: means a person applying to the Authority in pursuant to the provisions of the Biosafety Act, 2009 or those who wish to determine whether the genome edited products or processes are regulated by NBA.

Authority: means the National Biosafety Authority established under section 5 of the Biosafety Act, 2009;

Biosafety: means the avoidance of risk to human or animal health and safety, or the conservation of the environment;

Contained use: means any activity undertaken within a facility, installation or other physical structure which involves genetically modified organisms that are controlled by specific measures;

Conventional counterpart: means a closely related organism, its components and/or products for which there is experience of established safety based on common use.

Environment: includes the physical factors of the surroundings of humans and animals, including land, water, atmosphere, soil, vegetation, climate, sound, odour, aesthetics, fish and wildlife;

Foreign Genetic material: Refers to novel combination of genetic material from sexually non-compatible species through the use of modern biotechnology techniques;

Genetically modified organism: means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

Genome editing: means targeted methods to introduce new traits in organisms using various techniques which induce breaks in the DNA that can be repaired by endogenous mechanisms and lead to a range of changes at a targeted locus within the genome. This may be achieved by deleting, replacing, editing organism's own DNA or inserting a DNA sequence in the organism's genetic material;

Intentional introduction into the environment: means any deliberate use of genetically modified organisms beyond contained use;

Modern biotechnology: includes the application of—



- a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

- b) fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive and recombination barriers and which are not techniques used in traditional breeding and selection;

Novel combination of genetic material: means an organism whose DNA has been altered with the addition or substitution of foreign DNA.

Regulatory agency: means a regulatory agency as set out in the First Schedule of the Biosafety Act, 2009 or such other agency as the Minister may, by Order in the Gazette, determine;



CHAPTER ONE

1.0 THE NATIONAL BIOSAFETY AUTHORITY

1.1 Background

The National Biosafety Authority (NBA) is a state corporation in Kenya established pursuant to the provisions of the Biosafety Act, 2009 to regulate all activities involving genetically modified organisms (GMOs) in food, feed, research, industry, trade and environmental release. Being the national focal point on biosafety matters, NBA fulfils its mandate by ensuring and assuring safe development, transfer, handling and use of GMOs with the aim of ensuring safety of human and animal health as well as provision of adequate protection of the environment.

NBA has made great strides in establishing a strong Biosafety regulatory framework in Kenya by developing and publishing the implementing Biosafety Regulations namely; The Biosafety (Contained Use) Regulations, 2011; the Biosafety (Environmental Release) Regulations, 2011; the Biosafety (Import, Export and Transit) Regulations, 2011; and the Biosafety (Labeling) Regulations, 2012. These regulations lay down a clear procedure on handling GMOs whether plants, animals or microorganisms. NBA is the National Focal Point for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) and is mandated to implement the provisions of the Cartagena Protocol on all Biosafety matters pertaining to GMOs.

1.2 Vision Statement

A World-class Biosafety Agency

1.3 Mission Statement

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

1.4 Our Core Values

- a) Integrity
- b) Professionalism
- c) Transparency
- d) Accountability



1.5 Our Objectives

- a) To facilitate responsible research and minimize risks that may be posed by genetically modified organisms;
- b) To ensure adequate level of protection in the development, transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and
- c) To establish a transparent, science-based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities.

1.6 Our Core Functions

The Biosafety Act no.2 of 2009 lists the functions of NBA as follows:

- a) Consider and determine applications for approval for the development, transfer, handling and use of genetically modified organisms, and related activities in accordance with the provisions of the Biosafety Act;
- b) Co-ordinate, monitor and assess activities relating to the safe development, transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health and the environment;
- c) Co-ordinate research and surveys in matters relating to the safe development, transfer, handling and use of genetically modified organisms, and to collect, collate and disseminate information about the findings of such research, investigation or survey;
- d) Identify national requirements for manpower development and capacity building in biosafety;
- e) Advise the Government on legislative and other measures relating to the safe development, transfer, handling and use of genetically modified organisms;
- f) Promote awareness and education among the general public in matters relating to biosafety;
- g) Establish and maintain a Biosafety clearing house (BCH) to serve as a means through which information is made available to facilitate exchange of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms; and
- h) To exercise and perform all other functions and powers conferred on by the Act.



CHAPTER TWO

2.0 INTRODUCTION TO GENOME EDITING

2.1 Scope and Objective

2.1.1 Scope

These guidelines provide clarity on regulation of genome editing processes and their derived products. The guidelines apply to genome edited plants, animals and microorganisms under research, environmental release or placing in the market, import, export and transit. Determination of the regulatory process shall be conducted on a case by case basis.

2.1.2 Objective

With the emergence of genome editing technology, there is need to consider the appropriate regulatory mechanisms for products of such technology.

The objective is to provide guidance to users including applicants and reviewers on how genome edited organisms or products are regulated under the Biosafety Act, 2009.

2.1.3 Exemptions

These guidelines shall not apply to conventional breeding methods, mutagenesis, polyploidy, haploidy and other natural processes.

Any person or institution dealing with genome edited organisms or products shall make an application to the Authority for a determination of the regulatory process.

2.2 Rationale

Modern biotechnology, involving the use of recombinant-DNA (r-DNA) technologies, also known as genetic engineering, emerged as a powerful tool with many potential applications. Organisms modified using rDNA techniques, have been and are being developed with traits intended to provide benefit to farmers, consumers, and industry. These traits include; abiotic stress tolerances, disease resistance, herbicide tolerance, pest resistance, improved nutrition, improved shelf life, more efficient vaccines, faster growth, and production of useful by-products, among others.

The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) is the main international reference instrument for GMO regulation and Kenya is a signatory having signed in the year 2000 followed by ratification in 2003. Kenya's Biosafety laws are a domestication of the CPB. Under the protocol, GMOs referred to as living modified organisms are defined to mean any organism that possesses a novel combination of genetic material

obtained through the use of modern biotechnology techniques. Genome editing techniques may alter the genome of organisms resulting in either a GMO or organisms that are not distinguishable from those developed from conventional breeding or natural selection.

Regulators around the world have been developing regulations to assess and make decisions on genome editing techniques. The Authority, in consultation with relevant stakeholders, has taken the initiative to develop these guidelines to establish the regulatory mechanisms taking into consideration other international guiding documents and genome editing regulations from other countries.

Genome editing is an evolving technology and therefore regulatory frameworks developed need to be continually updated to ensure a facilitative review process. It is in this context that these guidelines have been developed in order to provide guidance to users including applicants and reviewers on the criteria for determining how genome editing techniques, organisms and derived products are regulated in Kenya.

2.3. Genome Editing Techniques

Advancements in genome sequencing, comparative analysis and functional genomics, have motivated researchers to look at new ways to develop improved traits by altering gene functions in a targeted manner. Different genome editing techniques have been developed and are in use. These guidelines shall apply to the techniques in the table below and any others that shall developed from time to time

(Table 1).

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Table 1: Genome Editing Techniques

Genome editing technique	Description
1) Oligonucleotide Directed Mutagenesis (ODM)	Oligonucleotide Directed Mutagenesis (ODM) involves specific nucleotide changes and, without the use of enzymes (e.g. nucleases), resulting in targeted single nucleotide polymorphisms (SNPs).
2) Site-Directed Nuclease (SDN)	Set of techniques based on the use of nucleases that introduce breaks in the DNA chain near a defined target sequence. Depending on the type of the endogenous DNA repair mechanism, different kinds of site-directed modifications or genome editing possibilities may lead to indel mutations, gene replacement, gene insertion, and site-directed structural rearrangements.
a) Meganuclease Technology	Meganucleases are naturally occurring restriction enzymes isolated from bacteria and yeasts that recognize and cleave DNA sequence targets, typically from 12 to 40 bp.
b) Zinc Finger Nuclease Technology	Zinc finger nucleases (ZFN) are proteins composed of a zinc finger part and a nuclease part. The zinc finger protein binds to a specific DNA location on each side where the nucleases perform their function in pairs. Zinc finger sequence can be adjusted such that the nucleases can cut a target sequence in the genome.
c) TALEN (Transcription Activator-Like Effector Nuclease) Technology	A type of site-directed nuclease that combines a customizable array of protein modules, found in bacterial proteins called transcription activator-like effectors, that each recognize a single DNA base and the catalytic domain of a DNA cutting enzyme called <i>FokI</i> . Examples of products developed with this technology include soybean edited to produce high oleic oil content



d)	CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)/Cas Technology	<p>i. Classic CRISPR/Cas: precise form of site-directed nuclease technology based on CRISPR/Cas bacterial defense system against viruses. The nuclease is coupled to a guide RNA which binds to a specific DNA site to elicit targeted DNA changes. Examples of products developed with this technology include increased lean muscle yield in cattle; tolerance to Bovine Viral Diarrhea Virus (BVDV)</p> <p>ii. DNA-free- CRISPR/Cas: in the classic CRISPR/Cas technique a vector is designed that includes the desired gRNA and Cas coding sequences. For DNA-free CRISPR/Cas recombinant Cas and in vitro translated gRNA are used. The ribonucleoprotein (RNP) complex is formed in vitro and is directly delivered to the protoplasts by e.g., polyethylene glycol (PEG) mediated fusion. The complex is already active and can directly detect its target to induce double strand breaks. Cell repair mechanisms lead to changes at the desired target without addition of any foreign DNA. The CRISPR/Cas complex is degraded within the cell and not integrated.</p>
e)	Prime editing	Prime editing combines a Cas9 enzyme with an engineered reverse transcriptase to directly write new genetic information into a targeted DNA site without causing double-strand breaks (DSBs). The pegRNA directs the Cas9-RT complex to the target DNA sequence where after the Cas9 creates a single-strand break the RT uses the RNA template within the pegRNA to add, remove, or substitute nucleotides in the DNA.
3) Epigenome editing (Chromatin editing)	Unlike genome editing which targets coding regions (e.g., exons), epigenome editing targets transcriptional regulation. It adjusts gene transcription through the epigenome, directly targeting the root of dysregulation while leaving the primary DNA sequence intact.	
4) Base editing	This uses the base-excision repair which is an endogenous DNA repair pathway. DNA glycosylases recognize common DNA lesions and remove the affected base by cleaving the N-glycosyl bond in the process of base-excision repair. Generally specific for one lesion type. Common edits include C->T; A -> G	



CHAPTER 3

3.0 REGULATORY CONSIDERATIONS FOR GENOME EDITING TECHNIQUES

3.1 Considerations for regulation of genome edited plants, animals and microorganisms

Different approaches can be used to achieve targeted DNA breaks and collectively, these are often covered under the acronym site directed nucleases (SDNs), pointing out to the general principle of the technology to use a DNA cutting enzyme (nuclease) for the generation of the targeted (site directed) DNA break. Variants of SDN applications are often categorized as SDN-1, SDN-2, and SDN-3 depending on the outcome of the DNA double strand repair.

SDN-1 refers to the situation where SDN is used without a DNA repair template, resulting in targeted but non-specific genetic mutations. In this scenario, the DSB position on the DNA is precise, but the host cell's DNA repair is random, leading to nucleotide deletions, additions, or substitutions. Alternatively, SDN-1 can cause the removal of larger DNA regions, such as a promoter or an entire gene, if two DSBs are induced on either side of a specific DNA sequence. In either of the cases, screening and selection are done to identify the desired genomic mutational outcome.

SDN-2: In this scenario, an SDN is used to produce a specific DSB, and a DNA repair template (a short DNA sequence identical to the targeted DSB DNA sequence but with one or a few nucleotide alterations) is employed to repair the DSB. This results in a specific and predetermined point mutation in the gene of interest.

SDN-3: When SDN is used along with a DNA repair template containing a new DNA sequence, such as a gene, the result of the editing would be insertion of that DNA sequence into the organism's genome. The most probable application demonstrating the use of SDN-3 would involve insertion of transgenic expression cassettes at a specific location within the genome.

Based on these different variations of genome editing, the Authority shall make determination on the regulatory pathway to be followed for genome edited organisms or products based on the following parameters:

- i. Insertion of foreign genetic material
- ii. Whether the genome editing leads to a new hazard, a compositional (nutritional) alteration, or other safety concern in the genome edited organisms or products
- iii. In cases where research and developmental phase starts with a GMO, NBA will regulate these genome edited organisms as GMOs up to the stage where foreign DNA is removed or segregated

3.2. Review Process

An applicant is required to submit an Early Consultation Form (Annex 1) and pay the applicable fees to the National Biosafety Authority (NBA) providing data on the experimental processes and end product to establish how it should be regulated under the Biosafety Act, 2009. For all Early Consultation Applications that are still under research phase, the Application has to be approved by the Institutional Biosafety Committee (IBC) or any relevant Scientific Committee

recognized by the relevant regulatory Authority responsible for Science, Technology and Innovation on submission of certificate of recognition, before submission of the application to the Authority.

On receipt of a genome edited application, it shall be screened for administrative completeness. If complete, technical screening shall commence, otherwise, it shall be referred back to the Applicant to provide the missing information. The report of technical screening shall be tabled at the Internal Technical Committee (ITC) for review and recommendations to the Chief Executive Officer (CEO). The CEO shall consider the recommendations and issue the decision document within 30 days and brief the Technical Committee of the Board, or revert to the ITC with reasons. Where there's need for further guidance by the Board, for example, when there's no concurrence between the CEO and the ITC, the report of the ITC together with the CEO's comments shall be forwarded to the Technical Committee of the Board for decision making within 90 days. The decision thereof is made on a case-by-case basis.

3.3. Handling of Confidential Information

The Applicant will be required to follow due process in case they want certain information to be considered as confidential business information (CBI). The Authority shall allow an Applicant to identify information provided in accordance with the requirements to be treated as confidential with justification for claims of confidentiality to be provided upon request, and upon payment of the applicable fee.

3.4. Review of decision

NBA reserves the right to alter its decision on request by the Applicant, or on its own volition if new scientific information previously unknown becomes available.

3.5. Monitoring

Upon approval, all genome edited organisms or products shall be monitored for unintended effects as appropriate for the duration of the approval. Additionally, the Authority reserves the right to independently undertake confirmatory tests to ascertain absence of any foreign genes or any regulatory tests that may be needed to ensure compliance to biosafety laws.

3.6. Offences and Penalties

A person who contravenes the provisions of these guidelines commits an offence and is liable on conviction to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years.

3.7. Review of the Guidelines

These guidelines will be reviewed every three years or any other time as may be required.



ANNEX

ANNEX 1: APPLICATION FOR EARLY CONSULTATION ON GENOME EDITING TECHNOLOGY IN KENYA

This form will guide in determining how genome edited organisms and their derived products are regulated in Kenya.

TITLE OF THE APPLICATION
SECTION I
1.1 Applicant Information
Name of Applicant: Affiliated Institution: Address: Email: Telephone:
1.2. Collaborators (Where applicable)
Address: Email: Telephone: Affiliated Institution: Website:
SECTION II: NATURE AND IDENTITY OF GENOME EDITED ORGANISM / PRODUCT
2.1. Taxonomic description of the organism: Genus, Species (Breed/ Strain/ Variety/ Line – where applicable)

SECTION III: PURPOSE OF GENOME EDITING

3.1. Introduced Trait:

3.2. Type of Application (Tick as appropriate)

Research

Import

Environmental release

Placing on the market

Others (specify)

For Research;

a). Location of research site:

b). Type of Trials (Tick as appropriate)

Lab

Greenhouse

CFT

NPT

Others (specify)

c). Objective

d) Has the project been approved by the Institutional Biosafety/Scientific Committee? Yes. No

(Attach IBC/ other Scientific Committee Minutes)

SECTION IV: MOLECULAR DESCRIPTION

4.1. Give a summary of the molecular techniques used:

4.2. Provide a description of the gene(s) or DNA sequence(s) modified:

4.3. Describe the outcome of the genome editing done (deletion, insertion, substitution, replacement, chromosomal rearrangements, etc, with supporting data)*;

4.4. Provide a description of the affected functions and pathways (where applicable)

4.5. Provide a description of the vectors used and their genetic maps
(where applicable)

4.6. If a vector was used, provide the following details:

4.6.1 Is the vector naturally pathogenic?

Yes No

4.6.2 Is the vector disarmed?

Yes No

4.6.3 If yes, how was the vector disarmed?

SECTION V: GENOME EDITED PRODUCT

5.1. Is the inserted foreign DNA sequence(s) present in the final product?

Yes No

If No;

5.1.1. Describe the techniques used to remove the inserted genetic sequences with the supporting data

5.1.2. Describe detection protocols used to confirm absence of inserted DNA sequences in the end products with supporting data;

5.2. Has the genome-edited product been commercialized anywhere in the World? If YES, where and for what purpose? Provide the unique identifier or trade name

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SECTION VI: DECLARATION OF CORRECTNESS OF INFORMATION

I certify that the above information is true to the best of my knowledge.

Principal Investigator/Applicant

Name _____

Signature _____ Date _____

Collaborator(s) (*if applicable*) Name(s)

Signature _____ Date _____

For research-based Applications only

Chairperson

Institutional Biosafety/ Scientific Committee

Signature _____ Date _____