National Biosafety Management Agency

NBMA

FEDERAL REPUBLIC OF NIGERIA

NATIONAL BIOSAFETY GUIDELINES ON GENE EDITING

December, 2020

Foreword

In our contemporary society, millions of people suffer from lingering malnourishment, occasioned by degrading agricultural systems and worsened by the loss of biodiversity and the increasing uncertainties of climate change. With the global population estimated to surpass 9 billion by 2050, agriculture will face increased challenges, requiring crops with higher yields, improved quality and needing fewer inputs.

There is a swift growth in modern biotechnological advancements aimed at addressing these issues and Nigeria cannot be left out amongst comity of nations who have embraced these emerging aspects. One of such advancement is Gene editing which provides cutting-edge biotechnological procedures that enable the precise and targeted modification of an organism's genome.

Gene editing has been known to produce great values in agriculture, medicine, and industry. It has been utilized in a wide selection of plant species to characterize gene functions and improve agricultural traits in terms of adaptation, resilience, high yield etc. This is quite evident in the improvement of the efficiency of plant and animal breeding, the introduction of new methods for the management of pests and diseases, and the development of new antimicrobials.

Despite the promise that Gene editing holds for global food security, the use of the products is affected by safety concerns. As with any technology, irrespective of its tremendous benefits, there is need for appropriate regulation, for the protection of man and the environment from potential risks that may be associated with it. The Federal Government of Nigeria recognizing this, amended the National Biosafety Management Agency Act, 2015 to provide a regulatory framework to safeguard humans, plants and the environment from Potential adverse impact that may be associated with the deployment of the technology. One of these regulatory instruments is the development of the National Bosafety Guidelines on Gene Editing by the National Biosafety Management Agency.

Accordingly, In December 2019, a 13-man expert committee, was inaugurated by NBMA to develop a draft document that would best fit Nigeria, taking into consideration the health and safety of the people, biodiversity and environment.
These guidelines after exhaustive discussions were validated. As science is not an issue of democracy, every intervention and modification made was backed up by superior scientific explanations and NBMA Act. 2015 (as amended).

In this document, step-by-step processes for Applicants that wish to carry out any form of gene editing are detailed, as Nigeria's regulatory approach for gene editing focuses on both the process and the product, on a case by case basis. The definition of GMOs as enshrined in the NBMA Act 2015 (as amended) principally determines products that would be given clearance and those that would go through full biosafety regulatory process.

The National Biosafety Management Agency owes many thanks to partners that provided assistance in reviewing the guidelines, namely: African Union Development Agency- New Partnership for Africa's Development (AUDA-NEPAD), Programs for Biosafety Systems (PBS), , Federal Ministry of Justice, Agricultural Research Council of Nigeria (ARCN), Nigeria Agricultural Seed Council, National Agricultural Quarantine Service (NAQS), National Biotechnology Development Agency, Biotechnology Society of Nigeria (BSN), Sheda Science and Technology Complex (SHESTCO), National Biotechnology and Biosafety Consortium (NBBC) and all the other stakeholders that took time to offer their thoughts which have shaped the final outcome of this document.

Dr. Rufus Ebegba
Director General/CEO
National Biosafety Management Agency

CONTENT

PART 1 – INTRODUCTION

In August 2019, the National Biosafety Management Agency (NBMA) Act, 2015 was amended to include the regulation of emerging aspects of modern biotechnology which are gene drive, gene editing and synthetic biology, and to ensure biosecurity, as well as related matters. Thus, the amendment comprises the insertion of section 25(A), which states:

"A person, institution or body shall not carryout gene drive, gene editing and synthetic biology except with the approval of the Agency".

Nigeria is a party to the Cartagena Protocol on Biosafety (CPB) and in accordance with the general provisions in Article 2 of the CPB, each party shall take necessary and appropriate legal, administrative and other measures to implement its obligations. Pursuant to this, the National Biosafety Management Agency (NBMA) Act, 2015 (as amended) (hereinafter referred to as "the Act") empowers the National Biosafety Management Agency (NBMA) (hereinafter referred to as "the Agency") to provide safety standards, guidelines and rules to facilitate its implementation; hence, the development of the National Biosafety Guidelines for Gene Editing, (hereinafter referred to as "the Guidelines").

The Act defines Genetically Modified Organism (GMO) as "any organism living or non-living that possesses a novel combination of genetic material obtained through the use of modern biotechnology" and Gene Editing as "a type of genetic engineering in which DNA is inserted, deleted, modified or replaced in the genome of a living organism". Gene Editing provides techniques that enable targeted and precise alteration of the genome with a high degree of specificity thus opening up new possibilities in their applications. The techniques include Transcription activator-like Effector Nucleases (TALENs), Zinc Finger Nucleases (ZFNs), Oligonucleotide-Directed Mutagenesis (ODM) and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR).

Gene editing techniques may alter the genome of an organism in a way that results in a new combination of genetic material or results in organisms that are not genetically distinguishable from those developed from conventional breeding/natural selection but obtained through genetic engineering/modern biotechnology.

Therefore, in line with the provisions of the Act and National Biosafety Implementation Regulations, 2017, gene editing and products thereof will be subject to appropriate Biosafety regulations on a case by case basis.

Consequently, Nigeria has adopted an approach to the regulation of gene editing and products thereof such that where the gene editing requires the use of recombinant DNA sequences or the gene edited product has a novel combination of genetic material (e.g. uses a recombinant DNA which remains in the final product), the product will be classified as a GMO and will be regulated as such. On the other hand, where the gene editing or the product thereof does not lead to or does not have a new combination of genetic material (e.g. does not use a recombinant DNA or uses a recombinant DNA which is removed in the final product), a non-GMO regulatory classification is applied.

Accordingly, these guidelines are for applicants wishing to carry out gene editing and the release of gene edited products in Nigeria.

This document, which stems from the above consideration, had been developed in consultation with line Ministries, Departments and Agencies in Nigeria, as well as with other relevant institutions and individual experts.

PART 2 – OBJECTIVE AND SCOPE

Objective:

The objective is to provide guidance and information on general regulatory provisions for applications for gene editing and products thereof.

Scope:

Information contained in the Guidelines are directed to all person(s), institution or body wishing to carry out gene editing as it relates to plants, animals and microorganisms ranging from containment, confined field trial, multi-locational trial, commercial/general release and imports intended for direct use as food or feed, or for processing.

The Guidelines apply to all gene editing and products thereof destined for use within the Federal Republic of Nigeria except for pharmaceutical processes and products, which are not covered by the Act.

PART 3 – GENERAL PROVISIONS FOR APPLICATION

Where gene editing and product thereof do not lead to or have a new combination of genetic material (e.g. do not use a recombinant DNA/uses a recombinant DNA, which is removed in the final product), a case by case regulatory provision leading to issuance of Biosafety Approval (Clearance), will apply.

On the other hand, where the gene editing process employs the use of recombinant DNA or the gene edited product has a new combination of genetic material (e.g. uses a recombinant DNA which remains in the final product), the regulatory classification stipulates that the final product is classified as GMO, and GMO regulation as provided in the Act and the National Biosafety (Implementation, etc) Regulations, 2017 will apply.

Accordingly, any person(s), institution or body wishing to engage in Gene Editing for any purpose must approach the Agency through the general provisions outlined in this Guideline.

I- Application for gene editing

Any person, group of persons, institution or company that intends to have dealings with Gene Editing for any purpose (containment, confined field trial, multi-locational trial, commercial release, import, export, food/feed/for processing and any other activity) shall apply to the Agency in the prescribed form contained in Annexure 2, obtained from the NBMA office or downloaded from the NBMA website - www.nbma.gov.ng and submit with relevant information, to the Agency.

II- Acknowledgement of Application by the Agency

The Agency shall, within 21 days, acknowledge in writing any application received to carry out any activity using gene editing as stated in the National Biosafety (Implementation, etc) Regulations, 2017.

III- Internal Review of the Application

The Agency will, within 21 days, after acknowledging the application:

i) internally review the application.
ii) request for additional information, if need be
iii) convey the decision of the internal review to the applicant

The decision of the internal regulatory review will indicate if:

a. a Biosafety Approval (Clearance) will be issued, where the product is found not to contain any recombinant DNA; or

b. the review of the application will continue further (in line with the Act and National Biosafety (Implementation, etc) Regulations, 2017) where the product is classified as GMO.

IV- Payment of Prescribed Application Fees by the Applicant

The applicant will be required to pay non-refundable fees as prescribed.

PART 4- DEFINITION OF TERMS

a) The terms used in the Act shall apply to these guidelines

b) In these guidelines-

"Act" means the National Biosafety Management Agency (NBMA) Act, 2015 (as amended).

"Applicant" means any person, institution, body or their authorised representative in Nigeria who applies for a biosafety permit or approval under these guidelines.

"Biosafety Approval" is an official document giving an applicant clearance, permit or authorisation to carry out particular activity as regards gene editing or product thereof.

"Clearance" is an official document issued to an applicant indicating that the gene edited product is not a GMO and does not require further biosafety regulation.

"Contained Use" means any operation using modern biotechnology undertaken within an enclosed facility, installation or other physical structure, such as a building, laboratory or greenhouse.

"Confined Field Trial" means a small-scale experimental release into the environment of a gene edited organism under physical and biological confinement conditions.

"DNA" means deoxyribonucleic acid. It is a molecule that carries genetic instructions in all living things which consist of two strands that wind around one another to form a double helix chain.

"Recombinant DNA" means deoxyribonucleic acid from sexually non-compatible species.

"Gene Editing" means a type of genetic engineering in which DNA is inserted, deleted, modified or replaced in the genome of a living organism.

"Genetic Engineering" means modern biotechnology

"Genetic Material" means any part of a plant or animal or microbe containing functional units of the heredity.

"Genetically Modified Organisms (GMOs) means any organism living or non-living that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

"Modern Biotechnology" means the application of:

(a) *In vitro* nucleic-acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles; or

(b) Fusion of cells beyond the taxonomic family,

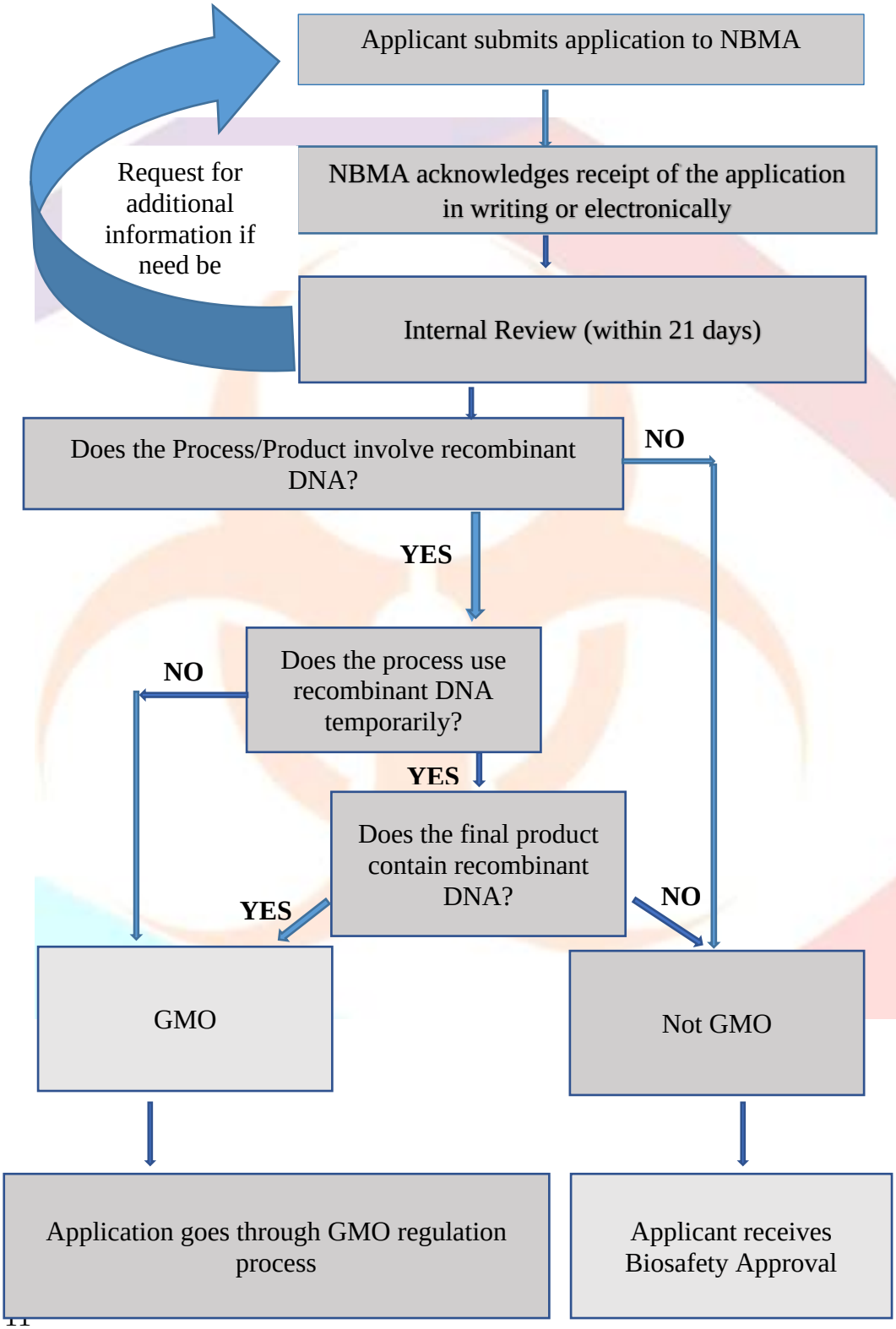
that overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection.

"Multi-locational Trial" means confined field trials conducted in two or more locations.

"Novel Combination of Genetic Material" means a combination of DNA sequences which is possible only through modern biotechnology and is not possible to find in nature or obtained through conventional breeding techniques.

ANNEXURE 1

FLOW CHART FOR NATIONAL BIOSAFETY GUIDELINES ON GENE EDITING



ANNEXURE 2

FEDERAL REPUBLIC OF NIGERIA

National Biosafety Management Agency
NBMA

BIOSAFETY APPLICATION FORM FOR GENE EDITING

Pursuant to section 25A of the National Biosafety Management Agency Act, 2015 (As Amended), this form shall be completed by persons, institution or body wishing to engage in Gene Editing activity.

PART A: GENERAL INFORMATION	
1. Name of Applicant	
2. Contact details a. Postal address: b. Telephone No: c. Email Address: d. Website (If any): e. Name of Contact Person: f. Email Address of Contact Person: g. Telephone No. of Contact Person:	
h. Proposed date of commencement of activity	

i. Preferred application mode (please tick)	☐ Manually ☐ Electronically
j. Preferred consultation mode (if you wish) (please tick)	☐ Face to face ☐ Phone call ☐ E-mail ☐ Virtual engagement
PART B: DESCRIPTION OF ORGANISM, GENE EDITING TECHNIQUES AND GENE EDITED PRODUCT	
1. Proposed scope of work	☐ Contained use ☐ Confined field trial ☐ Commercial release ☐ GMO-FFP ☐ Import ☐ Export
2. Common and Scientific name of the product (Organism) e.g. genus, species	
3. Gene Editing Activities • purpose of gene editing • summary of the gene editing techniques used or to be used and delivery methods • gene or DNA sequence(s) modified • type of gene editing done or to be done (deletion, insertion, substitution/replacement) • molecular description of the target organism's nucleotide target sequences, before and after gene editing (if applicable) • molecular description of the gene products, their functions and the affected pathways before and after gene editing (where applicable) • Name of vector(s) to be used or used, genetic map, pathogenicity, disarmed status and method of disarming (if disarmed).	
4. Is there any recombinant DNA to be used or used? (If No, kindly go to question 8) • If Yes, source of foreign recombinant DNA • If Yes, is it used temporarily? Where it is used temporarily (the final product is free of the	

recombinant DNA) describe the techniques used or to be used to remove the recombinant DNA and the detection protocols to be used or used to confirm absence of recombinant DNA in the gene edited product • If Yes, will the final product be free or is the final product free of the foreign recombinant DNA?	
5. Any expression of new or altered trait? If yes, state the trait.	
6. Product intended uses	
7. History of safe use of source of recombinant DNA and the product or the possible product history of safe use	
8. State any existing regulatory precedence for the gene edited product or gene editing process issuing country and purpose of the decision.	

PART C

CERTIFICATION

I certify that the information given above is correct and I understand the consequences of giving false information.

Name: _____

Signed: _____Date: _____

PART D

FOR OFFICIAL USE ONLY

Form Code _____

Remarks:

Signed: _____	Date: _____

Completed form should be returned to:
National Biosafety Management Agency,
National Parks Service Headquarters,
Umaru Musa Yar'Adua Express Way (Airport Road),
Abuja.

For further enquiries

Website: www.nbma.gov.ng
E-mail Address: nbma@nbma.gov.ng
GSM: +2348180805451