USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

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Report Name: Government of Nigeria approved National Biosafety Guideline on Gene Editing

Country: Nigeria

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Report Category: Biotechnology and Other New Production Technologies, Biotechnology and Other New Production Technologies Addendum, Biotechnology - Plants and Animals, Cloning

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Report Highlights:

In December 2020, the Government of Nigeria through the National Biosafety Management Agency (NBMA) authorized guidelines on gene editing. Nigeria takes this historic step in becoming the first country in Africa to issue gene editing guidelines. The government views science and technology as major drivers of agricultural productivity. The approved guidelines ensure that the technology is safe and does not have adverse impact on human health and the environment.

EXECUTIVE SUMMARY

Nigeria's Biosafety Bill was signed into law in 2015—establishing the National Biosafety Management Agency (NBMA), assuming biotech regulatory authority from the National Biotechnology Development Agency (NABDA). The NBMA is Nigeria's focal point and authority on biosafety, providing oversight for the use of biotechnology and regulating the commercialization of biotechnology products.

The Act charges NBMA with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in applying modern biotechnology in Nigeria. Furthermore, the Act also prevents any adverse effect of biotechnology on human health, animals, plants, and the environment.

The Agency believes that gene editing needs adequate regulation that will ensure that products being developed will not harm the environment, human and plants. NBMA worked with other sister agencies in drafting the guidelines, which was subsequently subjected to various internal and external reviews processes.

Tropical countries to which Nigeria belong is currently hosting more than two third of the world extremely poor people with a recent declaration of nutrition emergency in some parts of Northeastern Nigeria by the World Health Organization (WHO). In 2018, Nigeria was ranked the poverty capital of the world with an estimate of 90 million people said to be living in poverty. There is a link between food security, chronic hunger, and poverty. Poverty is a multifactorial concept that is both a cause and consequence of malnutrition and food insecurity. Nigeria views gene editing as a tool in resolving the myriad problems of agricultural productivity, and food insecurity including malnutrition, which is affecting vulnerable groups across the country. To deal with these complex challenges, the government is deeply vested in modern biotechnology.

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1.0 INTRODUCTION

Stakeholders in the agriculture and food security value chains in Africa are calling on their respective governments to ensure the continent is not left behind as gene editing revolutionizes food production globally. Gene editing is a reliable tool that can help enhance Africa's food security. Scientists are convinced that gene editing offers a new frontier for introducing advanced technology to tackle food security issues in Africa. Nigeria needs technologies such as gene editing to increase productivity, enhance the nutrition status of crops and animals and make them more resilient to climate change and a pandemic environment.

The Food and Agricultural Organization of the United Nations (FAO) has underscored five big challenges confronting agricultural systems across the world - escalating human population growth, increased life expectancy, biodiversity loss, climate change and accelerated land degradation. A technology-driven agricultural system is urgently needed in Nigeria to salvage potential food crises.

Currently, Nigeria is among many African countries confronting the challenges of food insecurity. The country has responded positively by amending the "National Biosafety Management Agency (NBMA) Act 2015" in August 2019 to accept emerging agricultural biotechnologies - gene drive, gene editing and synthetic biology, to ensure biosecurity, as well as food security. 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) 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 using 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 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 (also referred to as genome editing) is a set of molecular biology techniques that allow scientists to delete and silence specific genes, or otherwise manipulate the genomes of living organisms, to address productivity challenges in agriculture.

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. Additionally, genome editing technologies enable scientists to make changes to DNA, leading to changes in physical traits, like eye color, and disease risk. Scientists use different technologies to do this. These technologies act like scissors, cutting the DNA at a specific spot. Then scientists can remove, add, or replace the DNA where it was cut.

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 adopted an approach to regulate 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 that remains in the final product), the product will be classified as genetically engineered (GE) 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 that is removed in the final product), a non-GE 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.

2. 0 OBJECTECTIVE AND SCOPE OF THE GUIDELINE

Objective:

The objective is to provide guidance and information on general regulatory provisions for applications of 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 destined for use within the Federal Republic of Nigeria except for pharmaceutical processes and products, which are not covered by the Act.

3.0 GENERAL PROVISIONS FOR APPLICATION

The Guideline ensures that the process of application is seamless. NBMA pledges to adhere strictly to timelines for excellent service delivery.

In case where gene editing and Product 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:

- Internally review the application.
- Request for additional information if need be.
- Convey the decision of the internal review to the applicant.

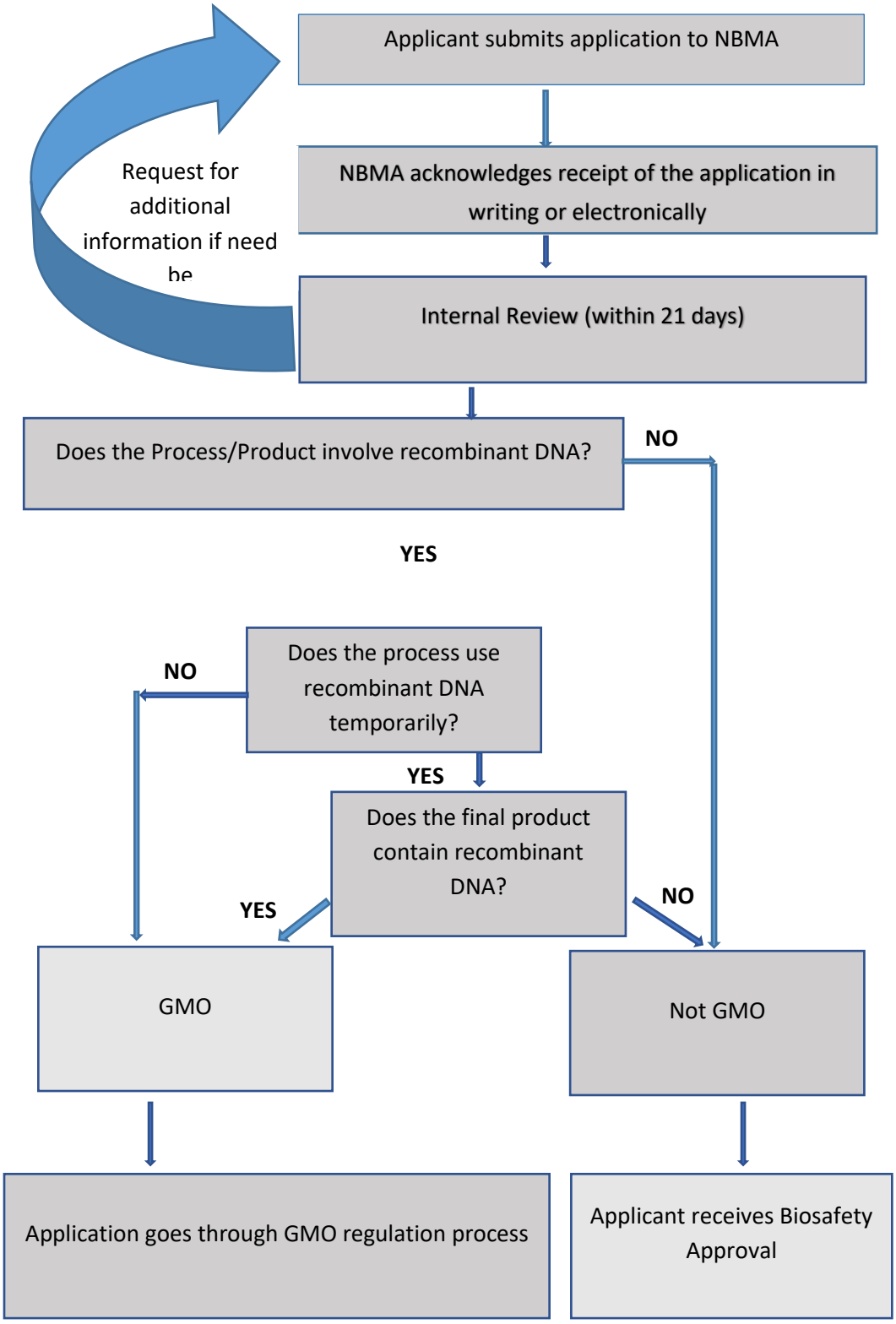
The decision of the internal regulatory review will indicate if:

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.

4.0 FLOW CHART FOR NATIONAL BIOSAFETY GUIDELINES ON GENE EDITING



5.0 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

6.0 CONCLUSION

Identifying the benefits of biotechnology in improving agricultural production, and food security, governments across Africa have taken steps to establish enabling policy frameworks to support adoption of biotechnology including GE crops and derived products.

The Government of Nigeria achieved this accomplishment through the creation of NBMA as an Agency under the Ministry of Environment specifically to handle designing of regulatory frameworks and approvals for biotechnologies. The nimble organizational structure adopted by the Agency allays the fears of over regulated regimes that pervade the development and deployment of new agricultural technologies.

Lagos FAS Office is investing resources to support collaborative relationships with both NABDA and the regulator NBMA. The two agencies are willing and always ready to collaborate with U.S. stakeholders.

KEY CONTACTS AND FURTHER INFORMATION

USDA/FAS CONTACTS

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Attachments:

No Attachments.