(Federal Ministry of Environment)

FEDERAL REPUBLIC OF NIGERIA

National Biosafety Guidelines

for

the Determination of the Regulatory Status of Progeny Lines and Hybrid Seeds Derived from Biotechnology-based Hybrid Seed Systems in Nigeria

2026

Federal Republic of Nigeria

Contents

Abbreviations **3**

FOREWORD **4**

1.0 INTRODUCTION **5**

1.1 Objectives **7**

1.2 Scope **7**

2.0 GENERAL PROVISIONS FOR APPLICATION **7**

2.1 Application Procedure **8**

2.2 In-Country Testing, Confirmatory Testing and Validity of Clearance **9**

2.2.1 In-Country Physical Testing **9**

2.2.2 Case-Specific Confirmatory Testing **9**

2.2.3 Validity of Clearance **9**

2.3 Acknowledgement of Receipt **10**

2.4 Review of Application **10**

2.4.1 Completeness Check **10**

2.4.2 Technical Review **11**

2.4.3 Payment of Prescribed Application Fees by the Applicant **11**

3.0 REGULATORY DECISION PATHWAYS **11**

4.0 MISCELLANEOUS **12**

4.1 Offences and Penalties **12**

4.2 Appeals **12**

Definition of terms **13**

ANNEX 1: APPLICATION FORM FOR DETERMINING THE REGULATORY STATUS OF PROGENY LINES AND HYBRID SEEDS DERIVED FROM BIOTECHNOLOGY-BASED HYBRID SEED SYSTEMS (BbHSS) ..... **Error! Bookmark not defined.**

ANNEX 2: FLOWCHART ON THE GENERAL PROVISIONS AND PATHWAYS FOR DETERMINING THE REGULATORY STATUS OF PROGENY LINE AND HYBRID SEED DERIVED FROM BIOTECHNOLOGY-BASED HYBRID SEED SYSTEMS (BbHSS) 15

Abbreviations

BbHSS:	Biotechnology-based Hybrid Seed Systems
CPB:	Cartagena Protocol on Biosafety
DH:	Double Haploid
DNA:	Deoxyribonucleic Acid
F_1:	First Filial Generation
GEd:	Gene Editing
GM:	Genetically Modified/Genetic Modification
GMO:	Genetically Modified Organism
MCS:	Multi-Control Sterility
MDAs:	Ministries, Departments and Agencies
NBMA:	National Biosafety Management Agency
NBTs:	New Breeding Techniques
SPT:	Seed Production Technology
TGHRT:	Third Generation Hybrid Rice Technology

FOREWORD

Biotechnology continues to provide significant opportunities to improve agricultural productivity, food security, economic development, and environmental sustainability. The emergence of biotechnology-based hybrid seed systems, however, requires clear and predictable regulatory approaches to ensure that innovation is responsibly promoted while human health, biological diversity and the environment are adequately protected.

The National Biosafety Management Agency (NBMA), in accordance with its mandate under the National Biosafety Management Agency Act, 2015 (as Amended), has developed the National Guidelines for the Determination of the Regulatory Status of Progeny Lines and Hybrid Seeds Derived from Biotechnology-Based Hybrid Seed Systems to provide a harmonized and transparent framework for determining the regulatory status of such derived products and the applicable biosafety requirements.

The Guidelines are intended to provide clarity and consistency to regulators, technology developers, breeders, researchers, seed companies and other stakeholders, while reducing regulatory uncertainty and facilitating responsible biotechnology innovation.

I commend the experts and stakeholders whose contributions have supported the development of this important document. I am confident that its effective implementation will strengthen Nigeria's biosafety regulatory framework and contribute to the responsible deployment of biotechnology for national development.

I encourage all relevant stakeholders to acquaint themselves with and adhere to these Guidelines and other applicable biosafety laws, regulations and standards.

DR. Fatima Suleiman Zuntu
Director-General/Chief Executive Officer
National Biosafety Management Agency (NBMA)

1.0 INTRODUCTION

Pursuant to the National Biosafety Management Agency Act, 2015 (as Amended), and consistent with Article 2 of the Cartagena Protocol on Biosafety (CPB), the National Biosafety Management Agency (NBMA) is mandated to regulate modern biotechnology and emerging technologies in Nigeria. Sections 3(a) and 41(3) of the Act empower the Agency to develop guidelines necessary for the safe use, management, and regulation of modern biotechnology, emerging technologies, and their products.

Biotechnology-based Hybrid Seed Systems (BbHSS) are emerging technologies that use molecular and genetic approaches to prevent self-pollination in hybrid seed production. These systems enable the efficient production of genetically uniform and high-purity F_1 hybrid seed through controlled cross-pollination between designated female and male parental lines. Examples include Seed Production Technology (SPT), Third Generation Hybrid Rice Technology (TGHRT), and Multi-Control Sterility (MCS) system. A key requirement in these approaches is the prevention of self-pollination in the female parent to maintain genetic purity.

In conventional hybrid seed production, self-pollination is prevented through manual or mechanical methods, such as detasseling in maize or emasculation in crops such as rice. These processes are labour-intensive, time-sensitive, costly, and often difficult to scale. BbHSS offers an alternative approach by generating male-sterile female parental lines through targeted modification of genes that control pollen or anther development. These male-sterile lines serve as the female parents in hybrid seed production systems.

Propagation of male-sterile lines requires a maintainer system. Maintainer lines may be developed through conventional breeding or through modern biotechnology, including genetic modification (GM) and New Breeding Techniques (NBTs) such as gene editing (GEd). Consistent with the NBMA regulatory framework, BbHSS that do not introduce recombinant DNA sequences in the final organism and do not possess a novel combination of genetic material are considered non-GM. Such plants may be indistinguishable from those developed through conventional breeding or naturally occurring mutations and are therefore regulated in accordance with the provisions applicable to non-GM products.

Transgenic maintainer lines typically contain a genetic construct comprising of:

(i) a fertility-restoration element to enable pollen production for propagation,

(ii) a pollen-control mechanism, which ensures that pollen grains carrying the maintainer construct are non-viable, to prevent transmission of the construct through pollen, and

(iii) a selectable marker for identification and separation of seeds carrying the maintainer construct from those without the construct.

These systems are designed to produce male-sterile progeny lines that do not contain the transgenic maintainer construct and are subsequently used as female parents in commercial hybrid seed production via the single-cross, double-cross, or three-way-cross hybrids.

The regulatory status of progeny lines and hybrid seeds derived from BbHSS shall be determined on a case-by-case basis. Depending on the system design and segregation efficiency, progeny lines, and the hybrid seeds derived from them, may either be non-transgenic (retaining no component of the transgenic maintainer's construct) and thus, non-GMO, or some seeds may retain components of the transgenic maintainer's construct and are thus classified as GMO. Accordingly, regulatory determination shall be based on the confirmed genetic composition of the progeny line(s) and derived hybrid seeds.

Under Nigeria's regulatory framework:

- progeny lines and derived hybrid seeds that contain recombinant DNA sequences or a novel combination of genetic material, or any component of the transgenic maintainer line's construct, are classified as GMOs and regulated under the NBMA Act, 2015 (as Amended) and National Biosafety (Implementation, etc.) Regulations, 2017.
- where such elements are absent (i.e., progeny lines and derived hybrid seeds that do not contain recombinant DNA sequences or a novel combination of genetic material or any component from the transgenic maintainer line's construct), a non-GMO regulatory classification applies.

Accordingly, these Guidelines provide the regulatory pathway for determining the status of progeny lines and hybrid seeds derived from BbHSS technologies in Nigeria.

These Guidelines were developed in consultation with relevant Ministries, Departments and Agencies (MDAs) in Nigeria, research institutions, regulatory institutions, academia, seed companies, private sector, civil society organizations, farmer groups, subject-matter experts and other relevant stakeholders.

1.1 Objectives

The objectives of these Guidelines are to:

(i) provide guidance to applicants on the general provisions applicable to dealings in progeny lines or hybrid seeds derived from BbHSS technologies;
(ii) clarify the application procedures and documentation requirements; and
(iii) define the technical requirements for determining the regulatory status of progeny lines and hybrid seeds derived from BbHSS technologies.

1.2 Scope

These Guidelines shall apply to any person, institution or body undertaking any dealings involving progeny lines or hybrid seeds derived from Biotechnology-based Hybrid Seed Systems in Nigeria.

2.0 GENERAL PROVISIONS FOR APPLICATION

Any transgenic maintainer line developed through modern biotechnology and/or gene-editing (GEd) techniques shall be subject to full regulatory oversight under the NBMA Act and associated regulations. Accordingly, the development, testing, and deployment of such transgenic maintainer lines shall require prior biosafety assessment and approval by the Agency, as applicable.

The requisite written approval shall be obtained from the Agency before undertaking any dealings, including research, field trials, multiplication, distribution, or commercialization, involving a transgenic maintainer line in Nigeria.

The regulatory status of downstream progeny lines and hybrid seeds derived from BbHSS technologies shall be determined on a case-by-case basis, taking into account their confirmed

genetic composition. In particular, the determination shall be based on whether the progeny line or derived hybrid seed contains recombinant DNA sequences or a novel combination of genetic material or any component of the transgenic maintainer line's construct, or otherwise.

Accordingly, any applicant seeking to carry out any dealings involving progeny lines or hybrid seeds derived from BbHSS shall comply with the provisions of these Guidelines.

2.1 Application Procedure

Any applicant seeking to undertake any dealings involving progeny lines or hybrid seeds derived from BbHSS technologies shall submit a formal application to the Agency using the prescribed form provided in Annex 1, in order to determine the regulatory status of the progeny lines and derived hybrid seeds. The application form may be obtained from the Agency or downloaded from its official website.

The completed application form shall be accompanied by the applicable supporting documents, which may include but not limited to the following:

- a description of the BbHSS production system;
- a description of the transgenic maintainer line, including its regulatory history and current regulatory status in relevant jurisdictions;
- a description of the biological mechanism by which transmission of the maintainer construct is prevented, eliminated, or segregated from the progeny line or hybrid seed;
- details of the selection, sorting, separation, or segregation method used to remove seeds containing the maintainer-line construct;
- quality-control records;
- identity preservation and chain-of-custody documentation;
- validation data demonstrating the effectiveness of the sorting, selection, separation, or segregation process; and
- targeted molecular, protein-expression, or other appropriate analytical data confirming the absence or presence of construct-specific element.

Applicants shall certify that all information submitted is accurate, complete and scientifically valid.

2.2 In-Country Testing, Confirmatory Testing and Validity of Clearance

2.2.1 In-Country Physical Testing

In-country physical testing may not be required where the application contains sufficient, scientifically robust, and internally consistent evidence demonstrating the absence of the transgenic maintainer-line construct, recombinant DNA, a novel combination of genetic material, or any construct-specific expression product in the derived progeny line or hybrid seed.

For the purpose of these Guidelines, such evidence may include validated molecular analytical data, quality-control records, sorting or segregation-validation records (which may be based on colour, fluorescence, or other validated phenotypic or marker-based separation methods, as appropriate to the BbHSS approach used), identity preservation and chain-of-custody documentation, construct-specific detection assays, protein expression analyses, and any other scientifically credible information acceptable to the Agency.

The Agency shall determine, on a case-by-case basis, whether the evidence submitted meets the technical threshold required and is sufficient to waive in-country physical testing.

2.2.2 Case-Specific Confirmatory Testing

The Agency may request case-specific confirmatory testing where there is a documented scientific or technical basis to question the reliability, completeness, or consistency of the information submitted by the applicant. Such a basis may include, but is not limited to, inconsistencies in molecular or analytical data; uncertainty regarding seed-lot identity, traceability, or chain of custody; inadequate production, sorting, segregation, separation, or quality control records; or evidence suggesting unintended transmission of the maintainer-line construct.

Any confirmatory testing requested by the Agency shall employ validated, construct-specific analytical methods appropriate for detecting the relevant maintainer-line construct, recombinant DNA sequence, novel combination of genetic material, or construct-specific expression product.

2.2.3 Validity of Clearance

Where the Agency determines that a progeny line does not contain recombinant DNA, a novel combination of genetic material, or any component of the maintainer-line construct, that determination may apply to other progeny lines derived from the same maintainer-line construct

and segregation system, provided that the applicant demonstrates that the underlying biological mechanism and construct are unchanged. A single application may cover multiple progeny lines derived from the same maintainer-line construct.

However, where additional progeny lines are subsequently introduced into Nigeria under an existing determination, the clearance holder shall notify the Agency prior to its introduction into the country. Upon notification, the clearance holder will get an administrative clearance to proceed.

A regulatory determination issued under these Guidelines shall remain valid unless:

- credible new scientific evidence indicates the possible presence of recombinant DNA, a novel combination of genetic material, or any component of the maintainer-line construct, or
- material changes occur in the maintainer-line construct, segregation mechanism, breeding system, or genetic composition relevant to the original determination.

Nothing in these Guidelines shall preclude the Agency from conducting compliance verification, inspection, monitoring, or other regulatory activities in accordance with the Act and applicable regulations.

2.3 Acknowledgement of Receipt

The Agency shall acknowledge receipt of a completed application in writing within twenty-one (21) days of receipt.

2.4 Review of Application

2.4.1 Completeness Check

The Agency shall conduct an administrative review of each application to determine whether it satisfies the Agency's prescribed submission requirements.

i. Where the application is complete, it shall proceed to technical review.

ii. Where the application is incomplete, the Agency shall notify the applicant in writing and specify the additional information required. A stop-the-clock mechanism shall apply and the review period shall be suspended until the requested information is submitted.

2.4.2 Technical Review

The Agency shall conduct a case-by-case technical review of the application, taking into account:

- the design and operation of the BbHSS
- the biological mechanism used to eliminate or prevent transmission of the maintainer-line construct
- the quality and robustness of the evidence demonstrating the presence or absence of recombinant DNA, a novel combination of genetic material, or components of the maintainer-line construct

Requests for clarification or additional information shall trigger a stop-the-clock and thus suspend the review period until the requested information has been received.

Upon conclusion of the review, the Agency shall issue a written determination.

2.4.3 Payment of Prescribed Application Fees by the Applicant

Applicants shall pay the applicable non-refundable fees as prescribed by the Agency.

3.0 REGULATORY DECISION PATHWAYS

Based on the outcome of the technical review, one of the following outcomes shall apply:

1. **Clearance (Non-GMO Determination)**
    - Issued where the progeny lines and derived hybrid seeds do not contain recombinant DNA sequences or a novel combination of genetic material or components of the transgenic maintainer line's construct
2. **Biosafety Regulatory Oversight (GMO Classification)**
    - Applies where the progeny lines and derived hybrid seeds contain recombinant DNA sequences or a novel combination of genetic material or components of the transgenic maintainer line's construct

The Agency shall formally communicate its regulatory determination to the applicant in writing within 21 days of acknowledging receipt of a complete application, excluding any stop-the-clock period. See details in Annex 2.

4.0 MISCELLANEOUS

4.1 Offences and Penalties

Any person who undertakes dealings involving progeny lines or hybrid seeds derived from BbHSS technologies without prior regulatory status determination by the Agency commits an offence and shall be subject to penalties in accordance with the provisions of section 35 of the NBMA Act, 2015 (as Amended).

4.2 Appeals

Any person, institution or body aggrieved or dissatisfied with a regulatory determination, decision, directive, condition, or action of the Agency under these Guidelines may seek administrative review or appeal pursuant to Section 30 of the NBMA Act, 2015 (as Amended).

Definition of terms

In these Guidelines,

Act means the National Biosafety Management Agency Act, 2015 (as Amended);

Agency means the National Biosafety Management Agency (NBMA);

Applicant means any person, institution, body or their authorized representative in Nigeria who submits an application for regulatory status determination under these Guidelines.

Biotechnology-based Hybrid Seed System (BbHSS) means a class of emerging technologies that apply molecular and genetic approaches to prevent self-pollination during hybrid seed production, thereby enabling the efficient production of genetically uniform and high-purity F_1 hybrid seed.

Clearance means an official document issued to an applicant by the NBMA confirming that a progeny line and derived hybrid seed is not a GMO.

Construct means the Recombinant DNA sequences comprising the gene (s) of interest and associated regulatory elements introduced into the transgenic maintainer line to confer the intended function.

Dealings means any activity undertaken in relation to progeny lines or hybrid seeds derived from BbHSS technologies, including but not limited to research, development, breeding, propagation, production, cultivation, multiplication, testing, storage, possession, handling, transportation, distribution, supply, sale, importation, exportation, release, disposal, or any other form of use thereof.

Detasseling means the removal of tassels from maize plants to prevent self-pollination.

Double Cross means a hybrid resulting from the cross of two single-cross hybrids involving four distinct parental lines.

Emasculation means the precise removal or inactivation of the anthers from a bisexual (hermaphrodite) flower prior to anthesis to prevent self-pollination.

F_1 hybrid seed means seed of the first filial generation resulting from a controlled cross between two genetically distinct parents.

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.

Hybrid seed means the offspring resulting from a cross between two or more genetically distinct parents.

Maintainer line means a plant line that is used to propagate or maintain male sterility traits in associated breeding lines.

Non-GMO means any organism that does not possess a novel combination of genetic material obtained through the use of modern biotechnology.

Novel Combination of Genetic Material means a combination of DNA sequences which is possible only through the use of modern biotechnology and does not occur naturally or cannot be obtained through conventional breeding techniques.

Progeny line (also referred to as inbred line or pure line) means a line developed through repeated self-pollination (selfing) or techniques such as Double Haploid (DH) technology to achieve homozygosity.

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

Single Cross is the first-generation (F_1) hybrid resulting from a cross between two distinct inbred parental lines.

Stop-the-clock means the suspension of a review or determination timeline under these Guidelines, which applies from the date the Agency issues a request for additional information to the applicant and continues until a complete response is received.

Three-way Cross is a hybrid resulting from the cross of a single-cross hybrid with a third inbred parental line.

Transgenic maintainer line means a maintainer line developed using modern biotechnology that contains recombinant DNA sequences or a novel combination of genetic material.

ANNEXES

ANNEX 1 : APPLICATION FORM FOR DETERMINING THE REGULATORY STATUS OF PROGENY LINES AND HYBRID SEEDS DERIVED FROM BIOTECHNOLOGY-BASED HYBRID SEED SYSTEMS (BbHSS)

Pursuant to section 25A of the National Biosafety Management Agency Act, 2015 (as Amended), this form shall be completed by an applicant seeking to carry out any dealings involving progeny lines or hybrid seeds derived from BbHSS technologies.

Applicant shall include additional information as attachment to this form where necessary.

PART A: GENERAL INFORMATION	
1. Name of Applicant	
2. Contact Details a. Physical address and post code: b. Postal address: c. Telephone No: d. Email Address: e. Website (If any): f. Details of Contact Person in Nigeria *(if different from above):* i. Name: ii. Address: iii. Email Address: iv. Telephone No.	
PART B: DESCRIPTION OF BbHSS DERIVED PROGENY LINES OR HYBRID SEEDS	

1. Common and Scientific Name of the Crop	
2. Biotechnology-based Hybrid Seed System Technology used e.g. SPT, TGHRT, MCS	
3. Description of the Progeny line (s) and/or derived hybrid seeds:	
4. Description of the BbHSS production system	
5. Description of the transgenic maintainer construct and its regulatory status	
6. Description of the breeding system (biological mechanism by which transmission of the transgenic maintainer construct is prevented, eliminated, or segregated away)	
7. Description of the segregation mechanism (selection, sorting, or separation method used to remove seed containing the maintainer construct)	
8. Evidence demonstrating absence of recombinant DNA sequences, a novel combination of genetic material or any component of the transgenic maintainer line's construct in the progeny lines or hybrid seeds, (e.g., lot-specific quality control records; identity preservation and chain-of-custody documentation; sorting/segregation validation data;	

and targeted molecular or protein-based confirmation data)	
9. Have you obtained any regulatory status determination elsewhere for the progeny line (s) or derived hybrid seed? ☐ YES ☐ NO If yes, in which country and what regulatory status was obtained? (attach evidence)	
10. Any additional information	

PART C

CERTIFICATION

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

Name: _____

Signature: _____Date: _____

PART D

FOR OFFICIAL USE ONLY

Form Code _____

Remarks:

Signature: _____Date: _____

Completed form should be returned to:
National Biosafety Management Agency,
Plot 3, Kalahari Close, off ICS Drive, Dakibiyu District, Jabi, FCT, Abuja.
E-mail Address: nbma@nbma.gov.ng
For further enquiries
Website: www.nbma.gov.ng
E-mail Address: nbma@nbma.gov.ng
GSM: +2348082254683

ANNEX 2 : FLOWCHART ON THE GENERAL PROVISIONS AND PATHWAYS FOR DETERMINING THE REGULATORY STATUS OF PROGENY LINES AND HYBRID SEEDS DERIVED FROM BIOTECHNOLOGY-BASED HYBRID SEED SYSTEMS (BbHSS)

