(Federal Ministry of Environment)

FEDERAL REPUBLIC OF NIGERIA

National Biosafety Guidelines for Transgenic Hybrid Crop Varieties Derived from Previously Approved Events

1. Preamble

In exercise of the powers conferred on it by sections 41 (3) of the National Biosafety Management Agency Act, 2015 (As amended), and of all other powers enabling it in that behalf, the Agency makes these Guidelines which shall be referred to as:

The National Biosafety Guidelines for the Transgenic Hybrid Crop Varieties Derived from Previously Approved Events

These Guidelines are developed to provide clarity on the regulatory status of transgenic hybrid crop varieties derived from previously approved events, particularly to ensure that the approval of a specific event is not construed as an automatic approval for the development, breeding, importation, commercialization, distribution or varietal release of every hybrid, variety or crop product containing such an event. Approval of a event is specific to the application, conditions and scope for which regulatory approval was granted and does not, in itself, confer unrestricted approval for subsequent combinations, hybrids or varieties incorporating the approved event.

2. Purpose

These Guidelines establish the biosafety regulatory requirements for the transgenic hybrid crop varieties developed from events that have previously been approved by the National Biosafety Management Agency (NBMA). The Guidelines ensure that each hybrid variety demonstrates acceptable agronomic performance, food safety, and regulatory compliance prior to commercial release in Nigeria.

3. Scope

These Guidelines apply to any dealing leading to the development of hybrids involving events previously approved by the NBMA.

4. Application to NBMA

Any applicant intending to carry out an activity leading to the development of hybrids for events previously approved by the NBMA, shall apply to NBMA before:

a) Development or breeding of a transgenic hybrid variety within Nigeria; or
b) Importation of a hybrid variety developed outside Nigeria.

The applicant 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, including consent note from the developer of the technology. Upon satisfaction, the NBMA will issue an Authorization Letter in respect of the Hybrid Varieties intended to arise from the previously approved events.

5. National Performance Trials (NPTs)

Every transgenic hybrid variety arising from previously approved event(s) shall undergo National Performance Trials (NPTs) prior to commercialization. The NBMA must be notified prior to the start of the NPTs.

The NPTs shall:

a) Be conducted across the relevant agro-ecological zones of Nigeria.
b) Be implemented through an NBMA-accredited institution.
c) Be carried out under the oversight of the Institution's Biosafety Committee (IBC).
d) Be subject to biosafety monitoring and compliance inspections by NBMA throughout the trial period.

6. Submission of Trial Report

Upon completion of the NPTs, the applicant shall submit to NBMA:

a) A comprehensive National Performance Trial Report specific to the hybrid variety; and
b) Any additional information required by NBMA for regulatory review.

7. Review and Approval

NBMA shall review the submitted reports and may request additional information where necessary.

Where the hybrid variety satisfies all biosafety regulatory requirements, NBMA shall issue a Transgenic Hybrid Variety Approval Certificate (Supplementary Permit, where applicable).

8. Commercialization and Varietal Release

Following the issuance of the Transgenic Hybrid Variety Approval Certificate, the applicant may wish to proceed to the National Varietal Release Committee (NVRC) for Varietal release registration.

9. Regulatory Fees

Applicable NBMA regulatory fees shall apply per hybrid variety.

10. Compliance

No transgenic hybrid crop variety shall be commercialized, distributed, marketed, imported/exported or submitted for varietal release in Nigeria unless it has obtained the requisite NBMA Transgenic Hybrid Variety Approval Certificate in accordance with these Guidelines.

Failure to comply with these Guidelines shall constitute a violation of the National Biosafety Management Agency Act and any applicable regulations made thereunder.