



NATIONAL BIOSAFETY AUTHORITY

PROCEDURE FOR INTRODUCTION INTO THE ENVIRONMENT, IMPORTATION AND PLACING ON THE MARKET OF GENETICALLY MODIFIED (GM) COMMODITIES IN KENYA

Background

The National Biosafety Authority is a State Corporation established under section 5 of the Biosafety Act, No. 2 of 2009 to exercise general supervision and control over the transfer, handling and use of genetically modified organisms (GMOs) with a view of ensuring safety of human and animal health and provision of adequate level of protection of the environment.

The Biosafety Act Sections 19, 20 and 21 provides that no person shall introduce into the environment, import or place on the market genetically modified organism (GMOs) without the written approval of the Authority.

This guideline provides the procedure for introduction of GMOs into the environment, importation and placing on the market of GM commodities in Kenya as provided for by the Biosafety Act, Biosafety (Import, Export and Transit) Regulations, 2011 and Biosafety (Environmental release) Regulations, 2011.

This procedure does not cover Applications for research which shall be processed as provided for by the Biosafety Act Section 18 and the Biosafety (Contained use), Regulations, 2011.

A) PROCEDURE FOR INTRODUCTION OF GENETICALLY MODIFIED ORGANISMS (GMOs) INTO THE ENVIRONMENT

This procedure applies to applicants wishing to introduce genetically modified organisms (GMOs) into the environment for planting purposes. The procedure shall entail;

1. Applicant completes and submits online, Part A of the First Schedule of the Biosafety (Environmental release) Regulations, 2011. The Applicant submitting such an application may opt to concurrently apply for placing on the market by filling Part B of the Application Form.

2. The application shall be accompanied by a cover letter and applicable fees of Ksh.850,000 as provided for in Regulation 5(2)(a) of the Biosafety (Environmental release) Regulations, 2011.
3. The application is then screened for administrative completeness and acknowledged thereof.
4. The Authority in consultation with other regulatory agencies and biosafety expert reviewers undertakes a comprehensive risk assessment involving safety assessment and environmental risk assessment in accordance with national and international standards. A socio-economic impact assessment shall also be undertaken on the GMO under review.
5. Public participation shall be undertaken through public notification in at least two widely circulated newspapers, Gazette notices and NBA website. Members of the public will be given 30 days to submit their written comments.
6. The issues raised in paragraphs 4 and 5 (if any) shall be addressed by the Applicant before a decision on the application is made by the NBA Board. The final decision shall be communicated to the Applicant by the CEO in 90-150 days.
7. If approved, the validity of the approval is for a maximum period of ten (10) years, renewable once. If the application is rejected, the CEO shall inform the applicant on the decision with reasons for the rejection. A summary of decisions on all GMO Applications shall be made publicly available through the Biosafety Clearance House (BCH).
8. Once biosafety approval is granted by the Authority, the applicant shall seek regulatory approvals from other agencies as per their specific mandates and laws.
9. For GM crops, varieties shall only become available to farmers after variety testing and official release by the National Variety Release Committee (NVRC).
10. Once commercialized, NBA shall undertake post-market monitoring and surveillance of the GMOs during the approval period to assess if there are any unanticipated effects and performance of the approved GMO.

B) PROCEDURE FOR IMPORTATION OF GMOS AND/OR DERIVED PRODUCTS FOR PLACEMENT INTO THE MARKET

This procedure applies to importation of GMOs or their derived products for placement into the market, which have been assessed and approved in another country in accordance to international safety standards. The procedure shall entail;

Pre-shipment processes

- 1) The Applicant shall register with the National Biosafety Authority in the prescribed manner.

Application for placing on the market

- 2) The Applicant shall complete and submit online, Application Form for Placing on the Market of GMOs (Part B of the First Schedule of the Biosafety (Environmental release) Regulations, 2011.
- 3) The application shall be accompanied by a cover letter and applicable fee of Ksh.850,000 as provided for in Regulation 6(2)(a) of the Biosafety (Environmental release) Regulations, 2011.
- 4) NBA through the Internal Technical Committee (ITC) shall review the information provided and make a decision within **30 days** if the application falls under Section 28 of Biosafety Act on non-assessment of risks, otherwise a full risk assessment shall be conducted, and a decision made within **90-150 days**.
- 5) If approved, the CEO shall issue an approval document for placing the GMO on the market as provided for in the Second Schedule of the Biosafety (Environmental release) Regulations, 2011. The approval shall be exclusive to the Applicant, the approved GM Event(s) and species, and shall be valid for a period specified in the approval document but not exceeding ten (10) years.
- 6) If an application is rejected or a decision thereon is deferred, the CEO shall issue a notification to the applicant with reasons for the decision.

Application for import

- 7) Once the applicant receives the approval document for placing on the market (paragraph 5 above), the applicant shall complete and submit online, the Import Application Form (Third Schedule of the of the Biosafety (Import, Export and Transit) Regulations, 2011 accompanied by applicable fees of Ksh. 25,000.

- 8) If the application referenced in paragraph 7 is approved, the CEO shall issue an Import Approval Document as provided for in Second Schedule of the Biosafety (Import, Export and Transit) Regulations, 2011. The approval shall be exclusive to that consignment and will specify the conditions of approval.
- 9) If an application referenced in paragraph (7) is rejected or the decision thereon deferred, the CEO shall issue a notification to the applicant with reasons for the decision.

Note 1: The applicant may make an application for a master permit with a provision for part-shipments of the same approved GM commodity, provided that the importation is done within 12 months from the date of approval.

Cargo clearance

- 10) Once the applicant receives the Import Approval Document referenced in paragraph 8, the applicant shall lodge an application in the Trade Facilitation Platform (TFP). The applicant shall upload the approval documents in the TFP and pay the applicable fees.
- 11) The Authority shall verify the submitted documents and upon confirmation of sufficiency, approve or refer back for amendment of the application.
- 12) On arrival of the consignment, the Authority shall perform physical inspection of the consignment at the port of entry, collect a sample as appropriate; and upon fulfillment of all requirements, authorize release of cargo.
- 13) The applicant shall ensure the GM product intended for importation for placement on the market is rendered unviable through milling or processing to prevent propagation. This may be done at the country of origin or the port of entry or other designated and NBA approved premises prior to placing on the market and release to consumers.
- 14) The millers/operators shall put internal quality controls for proper segregation between GM and non-GM products in the milling and handling processes in their premises.
- 15) The GM product shall be packaged and labelled in accordance with the Biosafety (Labelling) Regulation, 2012. The guidelines for labelling are also available on the NBA website.

Note 2: An import approval is valid for 12 months for the same GM commodity.

SIGNED

A handwritten signature in blue ink, appearing to read 'N. K. Ngetich', with a long horizontal stroke extending to the right.

**NEHEMIAH K. NGETICH
AG. CHIEF EXECUTIVE OFFICER
DATE: 18TH NOVEMBER 2024**