NATIONAL BIOSAFETY AUTHORITY

GUIDELINES FOR PACKAGING AND TRANSPORTATION OF GENETICALLY MODIFIED ORGANISMS (GMOs) UNDER RESEARCH

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FOREWORD

In today's rapidly evolving scientific and agricultural landscape, the safe and efficient transport of Genetically Modified Organisms (GMOs) is essential to ensure that their benefits are realized while minimizing any associated risks. GMOs, which include plants, animals and microorganisms and their derived products play a significant role in modern agriculture, medical field, industry, environment and biotechnology research. However, their unique characteristics necessitate stringent handling procedures to safeguard human health, environmental integrity, and regulatory compliance. The transport of GMOs under research involves specialized procedures to address potential risks, including containment, labeling, and emergency response protocols. These guidelines have been developed to provide a comprehensive framework that aligns with both Kenya's and international standards and regulatory requirements, ensuring that all stakeholders adhere to best practices. This document therefore serves as a critical resource for all entities involved in the transport of GMOs under research. By adhering to these guidelines, stakeholders will contribute to the responsible and secure handling of GMOs, supporting both innovation in biotechnology and the protection of our shared environment.

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ABBREVIATIONS

GMO-Genetically modified organisms

GM-Genetically modified

NBA-National Biosafety Authority

DEFINITION OF TERMS

Genetically modified organism means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques

Regulatory agency means a regulatory agency as set out in the First Schedule to the Act, or such other agency as the Minister may by Order in the Gazette, determine

Authority means the National Biosafety Authority established under section 5 of the Biosafety Act, 2009

Research means any activity undertaken within a facility, installation or other physical structure which involves genetically modified organisms that are controlled by specific measures

Primary container means a container immediately surrounding the GMO.

Secondary container means a container immediately surrounding the primary container.

Tertiary container means a container immediately surrounding the secondary container.

Transport means:

- movement of GMOs between one authorized physical containment facility and another;
- movement of GMOs between any points specified in the transport form;
- movement of GMOs from an authorized physical containment facility, or from storage outside of an authorized physical containment facility, to a confined field trial
- movement of GMOs imported into Kenya from a point of entry to an authorized physical containment facility;
- movement of GMOs to be exported from Kenya, to a point of exit from an authorized physical containment facility

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CHAPTER ONE

1.0 THE NATIONAL BIOSAFETY AUTHORITY

1.1 Background

The National Biosafety Authority (NBA) is a state corporation in Kenya mandated to ensure safety of human, animal health and provide adequate protection of the environment from harmful effects that may result from genetically modified organisms (GMOs). The Authority was established pursuant to the provisions of the Biosafety Act, 2009 to regulate all activities involving GMOs in food, feed, research, industry, trade and environmental release and it fulfills its mandate by ensuring and assuring safe development, transfer, handling and use of GMOs in Kenya.

Under Section 51 of the Act, the Cabinet Secretary is vested with powers to make Regulations for better carrying into effect the provisions of the Act in consultation with the Authority. Pursuant to this Section, the Cabinet Secretary in consultation with Authority published the following Regulations;

i. Biosafety (Contained use) Regulations, 2011;
ii. Biosafety (Environmental Release) Regulations, 2011;
iii. Biosafety (Import, Export and Transit) Regulations, 2011; and
iv. Biosafety (Labelling) Regulations, 2012.

Section 50 of the Act requires any person manufacturing or importing any genetically modified organisms to ensure that the handling, packaging and identification and transportation of GMOs is done in the prescribed manner.

This guideline provides the framework for the transportation of GMOs in Kenya in accordance with Article 18 of the Cartagena Protocol on Biosafety and Section 50 of the Biosafety Act.

1.2 Vision Statement

A World-class Biosafety Agency

1.3 Mission Statement

To ensure and assure safe development, transfer, handling and use of genetically modified organisms (GMOs) in Kenya.

1.4 Our Core Values

a) Good governance and Integrity

b) Professionalism

c) Customer Focus

d) Inclusiveness

1.5 Our Objectives

a) To facilitate responsible research and minimize risks that may be posed by GMOs

b) To ensure adequate level of protection in the development, transfer, handling and use of GMOs that may have an adverse effect on the health of the people and the environment; and

c) To establish a transparent, science-based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities.

1.6 Our Core Functions

The Biosafety Act no.2 of 2009 lists the functions of NBA as follows:

a) Consider and determine applications for approval for the development, transfer, handling and use of genetically modified organisms, and related activities in accordance with the provisions of the Biosafety Act;

b) Co-ordinate, monitor and assess activities relating to the safe development, transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health and the environment;

c) Co-ordinate research and surveys in matters relating to the safe development, transfer, handling and use of genetically modified organisms, and to collect, collate and disseminate information about the findings of such research, investigation or survey;

d) Identify national requirements for manpower development and capacity building in biosafety;

e) Advise the Government on legislative and other measures relating to the safe development, transfer, handling and use of genetically modified organisms;

f) Promote awareness and education among the general public in matters relating to biosafety;

g) Establish and maintain a Biosafety clearing house (BCH) to serve as a means through which information is made available to facilitate exchange of scientific, technical,

environmental and legal information on, and experience with, genetically modified organisms; and

h) To exercise and perform all other functions and powers conferred on by the Act.

CHAPTER TWO

2.0 Transportation of GMOs Under Research

2.1 Introduction

The safe and efficient transport of GMOs is crucial as they play a key role in agriculture, industry, medicine, environmental management and scientific research. Transportation of GMOs require specialized handling to ensure compliance to regulatory frameworks to minimize potential adverse effects on animals, humans and the environment.

2.2 Scope

These guidelines provide the requirements that shall be taken into consideration when transporting GMOs under research.

2.3 Objective

The purpose of these guidelines is to provide guidance to users on the transportation requirements of GMOs under research.

2.4 Exemptions

These guidelines do not apply to movement of GMOs from an area in an authorized physical containment facility to another area within the same facility. These guidelines also do not apply to approved commercialized GMOs.

2.5 Requirements for transportation of GMOs

a) The GMOs shall be packaged in a three-tier arrangement consisting of labelled primary, secondary and tertiary containers or otherwise exempted by the Authority based on the unique circumstances of the GMO. GMOs intended for research shall be transported in prescribed containers to prevent escape during transportation. The outermost package of the GMOs shall be labelled in a manner capable of notifying any other handler of the material that the item to be transported is, or contains a GMO, preferably using the internationally recognized UN3245 label for GMOs that are not toxic or infectious. It shall also contain the details of the consignor and consignee. Before the transportation of GMOs for research, a notification shall be given to the Authority and the relevant regulatory agency for escort purposes.

i) GM micro-organisms to be transported, shall be wholly contained inside a sealed, unbreakable primary container.
ii) GM plants shall be transported in sealed primary containers.

iii) Experimental animals shall be individually tagged, tattooed, ear tagged or ear notched, microchipped, or labelled to indicate that they contain GMOs.

iv) GM and non-GM animals, capable of interbreeding, shall be kept physically separated from each other during transport unless inter-breeding is not restricted. If the separation fails, then any non-GM animals shall be treated as GM animals.

b) Access to the GMOs shall be restricted to authorised personnel that are trained and experienced

c) Any materials transported with the GM micro-organisms (such as soil, anti-desiccation agents or soil substitute in the case of plants, or bedding materials or feed in the case of animals) shall be either retained with the organisms under containment or decontaminated after transport has occurred.

d) Any accidental release of the GMO while being transported shall be reported immediately to the Authority; both verbally and in writing within 24 hours providing the following information;

i) the circumstances of the accident;
ii) the nature of accident to assess the impact to human health and the environment
iii) the identity and the quantity of genetically modified organisms released;
iv) any emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment and human health.
v) Additionally, the person transporting the GMOs in collaboration with the affiliated research institution and in consultation with the Authority shall take all appropriate short term, medium term and long-term measures to avoid or mitigate any adverse impact of such accident on the environment and human health.

Transportation of all GMOs for contained use shall be accompanied by a Record of Transport document form in the annexure.

2.6 Escort of GMOs

Prior to the transportation of GMOs for research, a formal written request shall be made to the Authority and the relevant regulatory agency by the research institution for escort purposes. The GMOs shall be moved between the specified regions in the request letter in the presence the inspectors. Following successful escort of materials, a record of transport form in the annexure shall be duly filled by the shipping party and signed by both inspectors. In cases where the transported GMOs are stored at the research facility, in addition to the record of transport form, a record of storage form in the annexure shall be duly filled by the recipient party and signed by both inspectors.

2.7 Offences and Penalties

A person who contravenes the provisions of these guidelines commits an offence and is liable on conviction to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years or both.

2.8 Review of the guidelines

These guidelines will be reviewed every three years or any other time as may be required based on new scientific information.

Annexes

Annex 1: Record of transport form

NBA/CFT/FORM NO.1

NATIONAL BIOSAFETY AUTHORITY

RECORD OF TRANSPORT

This Record of Transport should be completed for every movement of genetically modified plant material. For movement /Transport of a single genetically modified plant material, complete the information on this page. For movement/transport of multiple items, complete and affix one or more copies of the inventory list.
Following completion of this record by the Trial Manager/PI, one copy should be forwarded to NBA and the original retained by the trial manager/PI.

Shipper		**Recipient**	
Last Name	First Name	Last Name	First Name
Company/ Organization/ Institution	Department/ Section	Company/ Organization/ Institution	Department/ Section
Address Telephone Facsimile		Address Telephone Facsimile	
Pre-Transport Check-Off		**Genetically Modified Material Identification**	
Primary Method of Transport		User Identification Number	NBA Authorization Permit No.
☐ Rail ☐ Road ☐ Air ☐ Ship ☐ Other, Specify:			
Name of Carrier	Telephone	Plant/ Animal Species	Specify Amount of

			Material Shipped
Primary Container ☐ Plastic Bag ☐ Paper Bag ☐ Other; Specify		Form of Material ☐ Plants ☐ Animals ☐ Transplants ☐ Microorganisms ☐ Others	Identify Any Treatment Of The Material
Type of Secondary Container:			
If Applicable, Type of Tertiary Container:			
To Be Completed by the Recipient			
Receipt of Consignment			
Condition of the Container ☐ New ☐ Used ☐ Sanitized (Specify) Method of Sanitization:		All Inventory Checked and Complete ☐ Yes ☐ No	All accompanying Documentation Received ☐ Yes ☐ No
Containers Confirmed Free of Plant Material Prior to Loading ☐ Yes ☐ No		Condition of Containers Primary Container ☐ Intact ☐ Breached Secondary Container ☐ Intact ☐ Breached Tertiary Container ☐ Intact ☐ Breached	
Accompanying Documentation ☐ NBA Release/Transport Permit ☐ NBA Notification Acknowledgement ☐ Copy of NBA Permit Conditions ☐ Other (Specify) Other:		Other Details on Condition of Containers or Documentation	

Consignment Verification		**Receipt Verification**	
Signature of Shipper	Consignment Date	Signature of Recipient	Receipt Date
Trial manager verification This activity has been carried out in compliance with NBA Approval conditions		Signature of Trial Manager	Date signed
Inspector verification This activity has been carried out in compliance with NBA Approval conditions		Signature of Inspector	Date signed

Annex 2: Record of Storage form

NBA/CFT/FORM NO.5

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RECORD OF STORAGE

Facility Certification No.:

This **Record of Storage** should be completed for each genetically modified plant material placed into storage and each **Record of Storage** should be identified with a unique inventory control number. One or more copies of the Record of Inventory can be attached to the **Record of Storage** to document any removals of material from storage.

The **Facility Manager** is the person designated as responsible for the genetically modified plant material in storage.

No material should be removed from storage for transport outside of the facility without completion of a Record of **Transport**. In the event of an **accidental release** of the genetically modified plant material during storage, the regulatory agency should be immediately notified by telephone and facsimile. The incident and any corrective action taken should be recorded on the **Record of Corrective Action form.**

Facility Manager		**Genetically Modified Material Identification**	
Last Name	First Name	User Identification Number	NBA Approval No.
Company/ Organization/ Institution	Department/ Section	Plant/ Animal Species	Specify Amount of Material Stored
Address Telephone Facsimile Electronic Mail		Form of Material ☐ Plant ☐ Animals ☐ Microorganisms ☐ Transplants ☐ Other (Specify)	Identify Any Treatment of the Material

Storage Facilities				
Building Name	Room Number or Description			
Address (If Different from Above)		**Inventory Information**		
		Amount of Material placed into Storage (Kg)	Date Stored	Storage Location
Termination of Record of Storage				
Reason for Termination of Storage		Signature of Recipient		Effective Date
☐ All Material Removed ☐ Destruction of Material ☐ Other (Specify)				
Trial Manager Verification This activity has been carried out in compliance with NBA Approval conditions	**Signature of Trial Manager**	**Date Signed**		
Inspector verification This activity has been carried out in compliance with NBA Approval conditions	**Signature of Inspector**	**Date signed**		