

ARRANGEMENT OF REGULATIONS

Regulation

PART I - PRELIMINARY

1. Citation.
2. Interpretation.
3. Objective.

PART II- APPLICATIONS

4. Application and requirements for import.
5. Unauthorised importation.
6. Application and requirements to export.
7. Application for transit approval.
8. Conditions for transit of genetically modified organisms.
9. Unauthorized transit of genetically modified organisms.
10. Unintentional release while on transit.

PART III - MISCELLANEOUS

11. Monitoring for compliance.
12. Genetically modified organisms register.
13. Review of decisions.
14. Registration of decisions with the National Biosafety Clearing House.
15. Confidential Information.
16. Offences and Penalties.

SCHEDULES

First Schedule: Application form for Import, Export and Transit of
Genetically Modified Organisms.

Second Schedule: Approval

THE BIOSAFETY ACT
(No.2 of 2009)

IN EXERCISE of the powers conferred by section 51 of the Biosafety Act, the Minister for Higher Education, Science and Technology makes the following Regulations-

THE BIOSAFETY (IMPORT, EXPORT AND TRANSIT)
REGULATIONS, 2011

PART I- PRELIMINARY

Citation. **1.** These Regulations may be cited as the Biosafety (Import, Export and Transit) Regulations, 2011.

Interpretation. **2.** In these Regulations unless the context otherwise requires-

-Authority \emptyset means the National Biosafety Authority established under section 5 of the Act;

-Biosafety Clearing-House \emptyset means a mechanism for exchange of scientific, technical, environmental and legal information and experience with genetically modified organism;

-competent authority \emptyset means an agency of another country responsible under its national law for the control or regulation of genetically modified organisms;

-contained use \emptyset means any activity undertaken within a facility, field, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures to provide safety for humans and the environment;

-contained use premises \emptyset includes a facility, field, installation or other physical structure in which contained use is undertaken;

-environmental release \emptyset means introduction into the environment of a genetically modified organism for which an approval has been granted in

The Biosafety (Import, Export and Transit) Regulations, 2011

accordance with the Biosafety (Environmental Release) Regulations, 2011;

-exportø means to take out of Kenya genetically modified organisms;

-genetically modified organismø means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

-importø means to bring into Kenya a genetically modified organism;

-transitø means the movement of genetically modified organisms through Kenya to another country.

Objective.

3. The objective of these Regulations is to ensure safe movement of genetically modified organisms into and out of Kenya while protecting human health and the environment.

PART II- APPLICATIONS

Application and requirements for import.

4. (1) A person shall not import a genetically modified organism without a written approval from the Authority.

(2) An application to import a genetically modified organism shall be in the form set out in the First Schedule to these Regulations and shall be accompanied by-

(a) a cover letter; and

(b) the prescribed fee.

(3) An application to import genetically modified organisms shall be made to the Authority and shall specify-

(a) the species or identity and amount of the genetically modified organism to be imported; and

(b) the proposed port of entry into Kenya;

(c) the intended purpose for the genetically modified organism provided that-

The Biosafety (Import, Export and Transit) Regulations, 2011

- (i) where the intended purpose is for contained use the Regulations on Contained Use shall apply;
- (ii) where the intended purpose is for environment release the Regulations on Environmental Release shall apply.

(4) An approval granted by the Authority shall be in the form set out in the second schedule to these Regulations.

(5) The Authority may opt not to undertake risk assessment where it had granted previous approval for import of the same genetically modified organisms from the same source.

(6) A person who contravenes sub-regulation (1) of this regulation commits an offence.

Unauthorized importation.

5. In the event of an import of a genetically modified organism for which no authorization has been granted, the Authority -

- (a) shall initiate remedial actions such as refusal of entry, destruction or set conditions of use ; and
- (b) may inform and advise the public, of such genetically modified organisms.

Application and requirement for export.

6. (1) A person shall not export a genetically modified organism without a written approval from the Authority.

(2) An application to export a genetically modified organism shall be made to the Authority in the form set out in the First Schedule to these Regulations and shall be accompanied by-

- (a) consent or approval for import issued by the competent authority of the importing country; and
- (b) the prescribed fee.

(3) An application to export genetically modified organisms shall specify-

- (a) the species or identity and amount of genetically modified organisms

The Biosafety (Import, Export and Transit) Regulations, 2011

- that is to be exported; and
- (b) the proposed port of exit from Kenya;

(4) The Authority shall, upon receipt of an application to export a genetically modified organism, confirm that the export meets the requirements of the importing country and may issue an approval to export the genetically modified organisms in accordance with the second schedule.

(5) The Authority shall give a copy of the approval to the relevant regulatory agency for authorization of export.

(6) A person who contravenes sub regulation (1) of this regulation commits an offence.

Application for transit approval.

7. (1) A person shall not transit a genetically modified organism, which is not destined for Kenya without an approval from the Authority.

(2) An application for transit of genetically modified organisms shall contain the information set out in the First Schedule to these Regulations.

(3) A person transiting genetically modified organisms shall ensure that the genetically modified organisms are appropriately packaged and transported in accordance with these Regulations and other applicable International standards.

(4) A person who contravenes sub-regulation 1 commits an offence.

Conditions for transit of genetically modified organisms.

8. (1) A person transiting genetically modified organisms shall provide a copy of the approval granted by the Authority or clearance at the port of entry and exit.

(2) An approval to transit shall include –

- (a) suggested methods for packaging and handling of genetically modified organisms imported through conveyor shipment which shall comply with the relevant international and national requirement for repackaging and handling of conveyor shipped commodities ;
- (b) a requirement that conveyor shipment shall meet import conditions under these Regulations;
- (c) a copy of the import permit issued by the receiving country indicating the quantities or volumes involved from the country of origin and that the consignment may contain genetically

The Biosafety (Import, Export and Transit) Regulations, 2011

modified materials.

- (3) The Authority shall liaise with the relevant regulatory agency to ascertain that the consignment at the port of entry and exit is consistent with accompanying documents.

Unauthorized transit of genetically modified organisms.

9. In the event of transit of a genetically modified organism for which no authorization has been given, the Authority-

- (a) shall initiate remedial actions such as refusal of transit, destruction or set conditions for transit; and
- (b) may inform and advise the public of such genetically modified organisms.

Unintentional release while on transit

10. (1) In the event of an accident involving genetically modified organism on transit it shall be the responsibility of the person transiting and the importer to ó

- (a) notify the Authority immediately both verbally and in writing of the accident; and
- (b) as soon as possible provide the Authority with information regarding-
 - (i) the circumstances of the accident;
 - (ii) the identity and the quantity of genetically modified organisms released;
 - (iii) the accident that is necessary to assess the impact to human health and the environment; and
 - (iv) any emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment and human health.
- (c) take all appropriate short term, medium term and long term measures are taken to avoid or mitigate any adverse impact of such accident on environment and human health.

(2) The Authority may inform and advise the public, of the accident.

(3) The Authority in consultation with the relevant regulatory agency shall

The Biosafety (Import, Export and Transit) Regulations, 2011

undertake necessary action to minimize risk to human health and environment.

PART III- MISCELLANEOUS

- Monitoring for compliance **11.** The Authority shall liaise with the relevant regulatory agency to monitor any imported genetically modified organisms for compliance with the requirements of these Regulations.
- Genetically modified organisms register. **12.** The Authority shall maintain a register, which shall contain all applications made to, and decisions made by, the Authority on genetically modified organisms.
- Review of decisions. **13.** Where the Authority or a person granted an approval under these Regulations considers that ó
- (a) a change in circumstances has occurred that may influence the approval or the conditions issued under the approval; or
 - (b) additional relevant scientific or technical information has become available,
- the Authority may on its own volition or on the request of the person granted the approval, review its decision.
- Registration of decisions in the National Biosafety Clearing House. **14.** The Authority shall register all decisions made under these Regulations in the National Biosafety Clearing House within thirty days of making the decision.
- Confidential information. **15.** (1) An applicant may indicate the information in the application that should be treated as confidential and shall give verifiable justification in such a case.
- (2) The Authority shall decide, after consultation with the applicant which information may be kept confidential and shall inform the applicant of its decision.
 - (3) The Authority shall not disclose to a third party any information considered to be confidential and shall respect Intellectual Property rights relating to the data received.
 - (4) The Authority shall not consider the following information as confidential-
 - (a) name and address of the exporter and importer;

The Biosafety (Import, Export and Transit) Regulations, 2011

- (b) unique identifier of genetically modified organisms;
- (c) a summary of the risk assessment; and
- (d) any method and plans for emergency response.

(5) Where the applicant withdraws the application, the Authority shall respect the confidentiality of the information declared.

Offences and penalties

16. A person who contravenes the provisions of these Regulations 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.

The Biosafety (Import, Export and Transit) Regulations, 2011

FIRST SCHEDULE (r 4(2) 6(2) 7(2))

APPLICATION FORM FOR IMPORT, EXPORT AND TRANSIT OF GENETICALLY MODIFIED ORGANISMS

1. Name, address (including physical address) and contact details of the importer/exporter	Type of application (Tick as appropriate)
	Import Export Transit
2. Contact details of the Competent authority as applicable.	2.1 Importing /Destination country
	2.2 Exporting country
3. Name, address and contact details of the supplier.	4. Country of origin
	5. Expected date of import/export/ transit
6. Common name, scientific name, commercial name or unique identifier code of the genetically modified organism.	7. Port: 7.1 entry into Kenya
	7.2 exit from Kenya
8. Evidence of approval of the genetically modified organism from the exporting country (Attach)	9. Consent for import from the destination country incase of transit.
10. The intended use of the genetically modified organism in Kenya and what it was used for in the exporting country	11. The quantity of the genetically modified organisms to be imported into Kenya
12. A summary of the risk assessment report	
12. Methods and plans for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures.	
13. Describe the emergency response plan in Kenya the event of an accident with the genetically modified organisms	

The Biosafety (Import, Export and Transit) Regulations, 2011

DECLARATION BY APPLICANT

I, í í í í í í í í í of P.O. Box No. í í í í í of (Company/ Institution) í í í í .í í .
ID No. í í í í í ., hereby declare that to the best of my knowledge and belief the particulars given in
this application are true and correct.

Declared by } _____
this day of } **DECLARANT**
at }

Before me
Commissioner for Oaths/Magistrate/Judge

The Biosafety (Import, Export and Transit) Regulations, 2011

SECOND SCHEDULE (r 4, 6, and 9)

APPROVAL

THE NATIONAL BIOSAFETY AUTHORITY

APPROVAL TO IMPORT, EXPORT AND TRANSIT* GENETICALLY MODIFIED ORGANISMS

APPROVAL NUMBER _____	DATE OF ISSUE _____ VALID UP TO _____
In accordance with regulation 4, 6 and 7 of the Biosafety (Import, export end transit) Regulations 2011, approval is hereby granted to export, import or transit* the genetically modified organism herein stated. The approval is granted to the applicant mentioned in this approval.	
1.0 Name of the Applicant	2.0 To import from
	2.1 Name and address of supplier
	2.2 Country of supplier:
3.0 Identity of the genetically modified organism	
4.0 Specification of the genetic modification	
5.0 Purpose	
This approval is granted subject to the following conditions-	
1. _____	
2. _____	
3. _____	

The Biosafety (Import, Export and Transit) Regulations, 2011

4. _____	
The applicant should meet the following requirements for conveyor shipment	
1. _____	
2. _____	
3. _____	
4. _____	
Name: Signature: The Chief Executive Office National Biosafety Authority	Place: Date

N.B. - the applicant shall make samples available to the Authority on request

- This approval is not transferrable
- ensure that any other relevant legal requirements have been met
- * - Please delete as appropriate

Made on, 2011.

HELLEN SAMBILI,
Minister for Higher Education, Science and Technology.