

(Legislative Supplement No. 34)

LEGAL NOTICE NO. 97

THE BIOSAFETY ACT

(No. 2 of 2009)

THE BIOSAFETY (IMPORT, EXPORT AND TRANSIT)

REGULATIONS, 2011

ARRANGEMENT OF REGULATIONS

Regulations.

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 for export.
- 7 – Application and requirement for transit.
- 8 – Conditions for transit.
- 9 – Unauthorized transit.
- 10 – Unintentional release while-on transit.
- 11 – Approval.

PART III – MISCELLANEOUS

- 12 – Monitoring for compliance.
- 13 – Genetically modified organisms register.
- 14 – Review of decisions.
- 15 – Registration of decisions with the National Biosafety Clearing House.
- 16 – Confidential Information.
- 17 – Products derived from genetically modified organisms.
- 18 – Offences and Penalties.

SCHEDULES

- First Schedule: — Application form for Import, Export and Transit of Genetically Modified Organisms.
- Second Schedule: — Approval
- Third Schedule: — Information required for safety assessment

ARRANGEMENT OF SECTIONS

PART I - GENERAL

PART II - APPLICATIONS

PART III - MISCELLANEOUS

THE BIOSAFETY ACT, 2009

(No. 2 of 2009)

IN EXERCISE of the powers conferred by section 51 of the Biosafety Act, 2009, the Minister for Higher Education, Science and Technology with confirmation of the Board makes the following Regulations:—

THE BIOSAFETY (IMPORT, EXPORT AND TRANSIT)

REGULATIONS, 2011

PART I—PRELIMINARY

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

2. In these Regulations unless the context otherwise requires—

‘accident’ means the unintended release of genetically modified organisms in the course of import, export or transit, which could pose present an immediate or delayed hazard to human health and the environment;

‘Authority’ means the National Biosafety Authority established under section 5 of the Act;

‘Biosafety Clearing House’ means a mechanism for exchange of scientific, technical, environmental, socio-economic and legal information and experience with genetically modified organism;

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

‘contained use’ 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’ includes a facility, field, installation or other physical structure in which contained use is undertaken;

‘environmental release’ means introduction into the environment of a genetically modified organism for which an approval has been granted in accordance with the Biosafety (Environmental Release) Regulations, 2011;

‘export’ means to take out of Kenya a genetically modified organism;

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

‘import’ means to bring into Kenya a genetically modified organism;

‘transit’ means the movement of genetically modified organism

Citation.

Interpretation.

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 wishing to import a genetically modified organism shall apply for and obtain 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) an application fee of twenty five thousand shillings.

(3) An application under Regulation 4 shall specify—

- (a) the species or identity and amount of the genetically modified organism proposed to be imported; and
- (b) the proposed port of entry into Kenya;
- (c) the intended purpose for the genetically modified organism:

Provided that —

- (i) where the intended purpose is for contained use the provisions of the Biosafety (Contained Use) Regulations, 2011 shall apply;
- (ii) where the intended purpose is for the environmental release the provisions of the Biosafety (Environmental Release) Regulations, 2011 shall apply.

(4) The Authority may opt not to undertake risk assessment in cases where it previously gave approval for importation of the same genetically modified organisms from the same source.

(5) 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 action such as refusal of entry, destruction or set conditions of use ; and
- (b) may inform and advise the public, of the existence of the genetically modified organism within the country.

Application and requirement for export.

6. (1) A person wishing to export a genetically modified organism shall apply for and obtain 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 and shall be accompanied by—

- (a) consent or approval for import issued by the competent authority of the importing country; and
 - (b) an application fee of twenty five thousand shillings.
- (3) An application to export genetically modified organisms shall specify-
- (a) the species or identity and amount of the genetically modified organism that is to be exported; and
 - (b) the proposed port of exit from Kenya.

(4) The Authority shall, upon receipt of an application under this regulation, confirm that the proposed export meets the requirements of the importing country and may issue the approval in the manner prescribed in 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.

7. (1) A person wishing to transit a genetically modified organism shall apply for and obtain written approval from the Authority.

Application and requirements for transit.

(2) An application under paragraph (1) shall be in the form set out in the First Schedule.

(3) A person transiting a genetically modified organism shall ensure that the genetically modified organisms are packaged and transported in accordance with Kenyan and International standards.

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

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

Conditions for transit.

(2) An approval to transit shall include –

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

9. If a person transits or is in the process of transiting a genetically modified organism for which no approval has been granted, the Authority may —

- (a) confiscate the genetically modified organism;
- (b) destroy the genetically modified organism; or
- (c) set conditions for transit of the genetically modified organism; and
- (d) inform and advise the public on the genetically modified organism.

Unintentional release while on transit.

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

- (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 organism released;
 - (iii) the type of accident; and
 - (iv) any emergency measures taken or that ought to be taken to avoid or mitigate any adverse effects of the accident.

(c) take all appropriate short term, medium term and long term measures to avoid or mitigate any adverse effects of the accident.

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

(3) The Authority in consultation with the relevant regulatory agency shall undertake necessary action to minimize risk to human health and environment.

Approval.

11. An approval granted by the Authority under these Regulations shall be in the form set out in the Second Schedule to these Regulations.

PART III—MISCELLANEOUS

Monitoring for compliance.

12. 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.

13. The Authority shall maintain a register, which shall contain all applications made to and decisions made by the Authority regarding genetically modified organisms.

Review of decisions.

14. Where the Authority or a person granted an approval under

these Regulations considers that—

- (a) a change in circumstances has occurred which 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.

15. The Authority shall register all decisions made under these Regulations in the National Biosafety Clearing House within thirty days of making the decision.

Registration of decisions in the National Biosafety Clearing House.

16. (1) The Authority shall not disclose to a third party any confidential information exchanged under these Regulation and shall protect the intellectual property rights of the applicant.

Confidential information.

(2) The applicant may indicate, with verifiable justification, information in the application the disclosure of which might harm the competitive position of the applicant and which should be kept confidential.

(3) The following information shall not be considered confidential—

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

(4) Where an applicant withdraws an application, the authority shall respect the confidentiality of the information supplied.

17. (1) A person intending to export, import or transit a product derived from genetically modified organisms whose safety has been established in accordance with Kenya Standards for food and feed safety assessment shall notify the Authority in writing indicating proof of safety.

Products derived from genetically modified organisms.

(2) The information required under sub-regulation (1) shall be provided in the format prescribed in the Third Schedule.

(3) Upon receipt of such notification, the Authority shall, in consultation with the relevant regulatory agency, review the information provided and communicate its decision.

18. 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.

Offences and penalties.

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)
	<input type="checkbox"/> Import <input type="checkbox"/> Export <input type="checkbox"/> 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 (in case of export or 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 organism to be imported into Kenya

12. A summary of the risk assessment report
13. Methods and plans for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures.
14. Describe the emergency response plan in Kenya in the event of an accident with the genetically modified organisms

DECLARATION BY APPLICANT

I, of P.O. Box No. of (Company/ Institution) ID No., 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

SECOND SCHEDULE (r.4(1), 6(1), 7(1),11)

APPROVAL TO IMPORT/ EXPORT /TRANSIT* GENETICALLY MODIFIED ORGANISMS

APPROVAL NUMBER _____	DATE OF ISSUE _____ VALID UP TO _____
In accordance with regulation 4, 6, 7 and 11 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/export/transit from/to
	2.1 Name and address of supplier:
	2.2 Country of supplier: 2.3 Country of destination:
3.0 Identity of the genetically modified organism	
4.0 Specification of the genetic modification	
5.0 Quantity approved	
6.0 Purpose	
This approval is granted subject to the following conditions-	
1. _____	
2. _____	
3. _____	
4. _____	

7.0 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

Note:

- 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

THIRD SCHEDULE

(r.17 (2))

INFORMATION REQUIRED FOR SAFETY ASSESSMENT

1. Name, address (<i>including physical address</i>) and contact details of the Applicant – include email and telephone.	Type of application (<i>Tick as appropriate</i>)
	<input type="checkbox"/> Import <input type="checkbox"/> Export <input type="checkbox"/> Transit <input type="checkbox"/> Other
2. Contact details of the competent authority responsible for safety assessment	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. Name of manufacturer or distributor if different from applicant.	7. Port: 7.1 Entry into Kenya
8.0 Description of the Product and its intended use	7.2 Exit from Kenya
9.0 Evidence of prior approval for use as food/feed and source or indication of where detailed information on the approval can be obtained.	10. Instructions and conditions of use, storage
11. Quantity of the product	12. Proposed labeling and packaging

Dated the 15th July, 2011.

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