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**THE ZANZIBAR ENVIRONMENTAL MANAGEMENT
ACT, NO. 3 OF 2015**

**ZANZIBAR BIOSAFETY REGULATIONS, 2024
[Made under section 86(2)(f)]**

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**THE ZANZIBAR ENVIRONMENTAL MANAGEMENT
ACT, NO. 3 OF 2015**

ZANZIBAR BIOSAFETY REGULATIONS, 2024
[Made under section 86(2)(f)]

**L.N. 103
of 2024.**

IN EXERCISE of the powers conferred upon me under section 86(2)(f) of the Zanzibar Environmental Management Act, No. 3 of 2015, **I, HARUSI SAID SULEIMAN**, Minister of State, First Vice President's Office, do hereby make the following Regulations:

Short title
and com-
mencement.

1. These Regulations may be cited as the Zanzibar Biosafety Regulations of 2024 and shall come into force after being signed by the Minister and published in the Gazette.

Application.

2. These Regulations shall apply to any activity in relation to the use of Genetically Modified Organisms and, or products thereof including:

- (a) importation;
- (b) exportation;
- (c) transit;
- (d) undertaking contained research;
- (e) undertaking confined field research;
- (f) commercialization; and
- (g) any other activity in relation to Genetically Modified Organisms and, or products thereof.

Interpreta-
tion.

3. In these Regulations, unless the context requires otherwise:

“Act” means the Zanzibar Environmental Management Act, No. 3 of 2015;

“Authority” means Zanzibar Environmental Management Authority established under section 14 of the Act;

“accident” means an unintended event that involve release or escape of Genetically Modified Organisms and, or products thereof;

“Biosafety Inspector” means a person designated under regulation 11 of these Regulations;

“Biosafety” means avoidance of risks relating to the protection of the environment, human and animals’ health as a result of Genetically Modified Organisms activities and, or products thereof;

“Confined field research” means any trial activity relating to the Genetically Modified Organisms at the confined area;

“Contained research” means any activity involving Genetically Modified Organisms conducted within a laboratory or a modern biotechnology production facility;

“export” means to transport out of Zanzibar Genetically Modified Organisms and, or products thereof through any port, airport or any other place in Zanzibar;

“Genetically Modified Organisms” has a meaning as ascribed to it under the Act;

“Genetically Modified Organisms activities” means import, export, transit, contained research, confined field research or commercialization of Genetically Modified Organisms and, or products thereof;

“import” means to bring into Zanzibar Genetically Modified Organisms and, or products thereof through any port, airport or any other place in Zanzibar;

“Minister” means the Minister Responsible for Environment;

“modern biotechnology” has a meaning as ascribed to it under the Act;

“modern biotechnology” has a meaning as ascribed to it under the Act;

“Prior-Informed Consent” means the provision of adequate risk assessment, avoidance and management information about a shipment of Genetically Modified Organisms and, or products thereof by the country of origin prior to the transshipment for the purpose of providing consent from the imported country;

“risk assessment” means recognized scientific analysis to assess potential adverse effects as a result of Genetically Modified Organisms activity;

“socio-economic assessment” means a consideration arising from the impacts of Genetically Modified Organisms on local communities, their livelihoods, the conservation efforts and sustainable use of biodiversity especially with regard to the value of biodiversity;

“transit” means transportation of Genetically Modified Organisms and, or products thereof through Zanzibar to Tanzania Mainland or to another country.

PART TWO

GUIDING PRINCIPLES, ADMINISTRATION AND INSTITUTIONAL ARRANGEMENTS

4. A person who is dealing with activity of Genetically Modified Organisms and, or products thereof shall be guided by the national and international principles of preventive, precautionary, transparency and accountability by considering the following: Guiding Principles.

- (a) lack of scientific evidence or certainty shall not be used as a basis for not taking precaution to prevent damage;
- (b) all approvals shall be made subject to compliance by the principle of precaution that involves the use of special techniques such as risk assessment, environmental impact assessment and economic and social assessment of the potential effects of the Genetically Modified Organisms activity; and
- (c) all approvals for Genetically Modified Organisms activities and, or products thereof shall be subject to a condition that the person is liable for fault liability principle for any damage caused to human health or environment.

5.-(1) The Ministry responsible for environment shall be a Focal Point for biosafety matters. Focal Point.

(2) The functions of the Focal Point shall be to:

- (a) coordinate biosafety issues in Zanzibar and establish link to the National Biosafety Focal Point;
- (b) develop national policies, guidelines and standard operating procedures on biosafety issues;

- (c) coordinate the establishment of administrative procedures that govern the import, export, transit, research and commercialization of Genetically Modified Organisms and, or products thereof;
- (d) coordinate on risk management measures and strategies to minimize or prevent identified potential risks;
- (e) coordinate biosafety capacity building programs to the public;
- (f) prepare annual reports and plans setting out its previous year's performance, ongoing and planned future of Genetically Modified Organisms activities and submit to Government; and
- (g) perform any other function for facilitating the implementation of these Regulations.

Establishment and composition of the Technical Committee.

6.-(1) There shall be a Technical Committee to be known as the Zanzibar Biosafety Technical Committee which shall be composed of:

- (a) Director of Environment who shall be the Chairperson; and
- (b) a representative from:
 - (i) Commission for Science and Technology, Zanzibar Office;
 - (ii) Zanzibar Chief Government Chemist Office;
 - (iii) Institution responsible for Agriculture;
 - (iv) Institution responsible for Livestock;
 - (v) Institution responsible for Health;

- (vi) Institution responsible for Fisheries;
- (vii) Institution responsible for Standards;
- (viii) Institution responsible for Food and Drugs;
- (ix) Higher Learning Institution;
- (x) Institution responsible for Trade,
- (xi) Institution responsible for Industry;
- (xii) Zanzibar National Chamber of Commerce;
- (xiii) Non-Governmental Organisation; and
- (xiv) Institution responsible for environmental enforcement and compliance.

(2) Members under sub regulation (1)(b) of this regulation shall be appointed by the Minister in consultation with the relevant institution and shall have the following qualifications:

- (a) at least first degree in the field of Natural science, environment and modern biotechnology studies; and
- (b) knowledge, skills and experience on Genetic Modified Organism or biosafety matters.

7. The Technical Committee shall regulate its own procedures in respect of its meeting.

8. The Technical Committee shall have the following functions:

- (a) conduct final technical review on the application associated with Genetically Modified Organisms activities and, or products thereof;

Proceedings
of meetings
of the
Technical
Commit-
tees.

Functions
of the
Technical
Committee.

- (b) prepare a report and recommendations of the reviewed application and advise the Minister whether to approve, reject, or impose specific conditions on the applications; and
- (c) perform any other function as assigned by the Minister for implementation these Regulations.

Designation and functions of competent authority.

9.-(1) There shall be a competent authority designated by the Minister in each ministry dealing with issues on Genetically Modified Organisms.

(2) The functions of the competent authority shall be to:

- (a) participate in the process of reviewing of applications of Genetically Modified Organisms activity and, or product thereof and make recommendations to Focal Point based on the findings of the review;
- (b) ensure compliance and enforcement and monitoring of Genetically Modified Organisms activity and, or products thereof within their sectors;
- (c) build capacity related to Genetically Modified Organisms activities and, or products thereof within their sectors;
- (d) conduct monitoring and evaluation of the activity related to Genetically Modified Organisms.
- (e) propose scientifically justified research pertaining to modern biotechnology and biosafety; and
- (f) perform any other function related to Genetically Modified Organisms activities and, or products thereof as assigned by the Minister.

(3) The Minister of respective ministry shall appoint not more than five member of the competent authority basing on their knowledge on biosafety matters, natural science, modern biotechnology or environment.

10.-(1) There shall be an institutional biosafety committee within the research institutions dealing with Genetically Modified Organisms which shall have the function to:

Institutional
biosafety
committee.

- (a) review an application of Genetically Modified Organisms activities and, or products thereof within their institutions and make recommendations on the findings;
- (b) assess their safety and compliance of applicable laws, regulations, guidelines and ethical considerations.
- (c) evaluate the potential risks and benefits associated with the proposed research and ensures that adequate containment and risk mitigation measures are in place;
- (d) conduct regular inspections and monitoring to ensure ongoing compliance;
- (e) establish protocols and procedures for reporting and investigating accidents or incidents relating to Genetically Modified Organisms activities and, or products thereof;
- (f) maintain appropriate documentation and records related to Genetically Modified Organisms activities; and
- (g) perform any other function as directed by competent authority for facilitating the implementation of these Regulations.

(2) The head of respective institution shall appoint members of the institutional biosafety committee basing on their knowledge on biosafety matters, natural science, modern biotechnology or environment.

Designa-
tion of the
biosafety
inspectors.

11. Without prejudice to the provisions of section 82 of the Act, the Director General shall designate among the authorized officers to be biosafety inspectors basing on their knowledge on biosafety matters, natural science or environment.

Duties
of the
biosafety
inspectors.

12.-(1) The biosafety inspectors designated shall have the following duties to:

- (a) inspect and monitor the sites, facilities, premises, vehicles, or any place where Genetically Modified Organisms research activity is taking place and, or where such genetic materials are stored, transported, planted or subjected to any other similar activity;
- (b) review documentation of proof on Genetically Modified Organisms activity and, or products thereof;
- (c) require information from any person who is dealing with Genetically Modified Organisms activity and, or products thereof;
- (d) enforce and ensure compliance of the terms and conditions of the permit issued under these Regulations; and
- (e) follow-up on any complain reported to the Focal Point.

(2) The biosafety inspectors shall prepare a report after conducting inspection and monitoring under subregulation (1)(a) of this regulation and shall submit it to the Focal Point.

13. The Focal Point may appoint independent experts on ad-hoc basing on knowledge in relevant field in modern biotechnology and Biosafety to assist in carrying out the following functions: Independent experts.

- (a) advising the Technical Committee;
- (b) reviewing and evaluate risk assessment of the Genetically Modified Organisms activities or products thereof that require additional expert opinion upon request by the Technical Committee;
- (c) performing socio economic assessment as per Zanzibar Genetically Modified Organisms Socio-economic Assessment Guidelines issued by the Minister under these Regulations upon request by the Technical Committee; and
- (d) performing any other functions as the Technical Committee may determine.

14.-(1) A person who has personal interest on the subject matter in any committee established under these Regulations shall declare his personal interest before the meeting and shall not participate in that discussion. Conflict of interest.

(2) Subject to the provisions of subregulation (1) of this regulation, a person who declares his personal interest shall be required to fill the interest declaration form as prescribed under the First Schedule of these Regulations.

PART THREE

PROCEDURES OF APPLICATION FOR GENETICALLY MODIFIED ORGANISM ACTIVITIES

15.-(1) A person who intends to undertake any Genetically Modified Organisms activity and, or products thereof in Zanzibar shall apply for a permit to the Minister by filling an application form as prescribed under Second Schedule of these Regulations. Applications for Genetically Modified Organism activities.

(2) A person making an application under this regulation shall pay application fee as prescribed under Third Schedule of these Regulations.

(3) Subject to sub regulation (1) of this regulation the applicant shall be required to attach the risk assessment report at the time of submitting his application.

(4) The Minister shall notify the applicant in writing after receiving the application under subregulation (1) of this regulation.

(5) The Minister shall conduct a preliminary review of the application submitted by the applicant and may request for an additional information where required.

(6) Upon completion of the preliminary review the Minister shall refer the application to the respective competent authority.

Technical
review and
analysis of
application.

16.-(1) Upon receiving an application from Minister, the competent authority shall conduct a technical review and analyze the application, and prepare a report stating its findings, reasons behind the findings and recommendations.

(2) The competent authority shall submit to the Focal Point the report attached with the processed application subject to subregulation (1) of this regulation.

(3) The competent authority shall refer the application to the respective institutional biosafety Committee for review and analysis, and shall prepare a report stating its findings, reasons behind the findings and recommendations.

(4) The competent authority, while evaluating the risk assessment report, shall take into account whether an application may benefit the country and contribute to sustainable development.

(5) The institutional biosafety committee shall, upon completion of the technical review, submit technical report with recommendations to the competent authority to be submitted to the Focal Point.

17.-(1) The Focal Point, upon receiving the report attached with the processed application from the competent authority, shall forward it to Technical Committee for review and analysis. Review by Technical Committee.

(2) The Technical Committee may, while making its final review and analysis have powers to:

- (a) request the Focal Point to engage independent experts to review the processed application with risk assessment and provide an independent report;
- (b) make inquiries from a competent authority for further clarification if needed;
- (c) request the applicant to answer questions and give clarification; and
- (d) request the applicant to furnish any other information that is necessary to guide the decision making process.

(3) The Technical Committee, upon completion of the review and analysis of the application, shall prepare a final report with recommendations and submit to the Focal Point.

18. The Technical Committee shall, before making its recommendations, consider and ensure the following: Matters to be considered before recommendations.

- (a) measures that need to be taken to minimize potential risks to humans, animals, biodiversity and environment are in place; and
- (b) mechanisms for monitoring are in place.

19.-(1) A person who applies to undertake Genetically Modified Organisms activities, shall undertake or cause to be undertaken risk Risk assessment.

assessment of the impacts and risks posed by the applied activity in accordance with the Risk Assessment and Management Guidelines.

(2) A report in respect of the Risk Assessment shall be prepared and submitted to the Focal Point and to be submitted to Technical Committee for evaluation.

(3) Without prejudice the provisions of subregulation (2) of this regulation, the Technical Committee shall produce an evaluation report of the risk assessment report stating the following:

- (a) scientific opinion;
- (b) grounds for decision;
- (c) recommendations, if any; and
- (d) matters for determination if any.

(4) An applicant who is undertaking a risk assessment shall bear the cost including the cost for review and evaluating the risk assessment report as prescribed under the Third Schedule of these Regulations.

Socio-economic
assessment.

20. The Technical Committee may cause a competent authority or independent experts to undertake socio-economic assessment of the application in accordance with the Zanzibar Socio-economic Assessment Guidelines before making a recommendation to the Minister to issue a permit.

Environ-
mental
Assessment.

21. A person who intends to carry out Genetically Modified Organisms activity and, or products thereof shall be required to conduct an Environmental Assessment in accordance with the Act or Environmental Assessment Regulations.

Duration
of the
application
process.

22. The Minister shall consider the application within ninety days from the date of receiving the application.

23.-(1) The Minister may decide whether to issue a permit with or without conditions or reject to issue a permit.

Issuance of permit.

(2) Where a decision is made to issue a respective permit, and upon payment of the fees prescribed under the Third Schedule of these Regulations by the applicant, the Minister shall issue a permit as prescribed under the Fourth Schedule of these Regulations.

(3) Where the Minister decides to reject the issuance of permit, shall inform the applicant in writing by stating the reasons for rejection.

(4) A permit holder who is permitted for research purpose under the provisions of these Regulations shall be subjected to other procedures for conducting research in Zanzibar.

24.-(1) The Focal Point shall set biosafety levels for contained research.

Classification of biosafety levels.

(2) Any permit granted for undertaking contained research of Genetically Modified Organisms shall be aligned with the biosafety levels as prescribed under the contained research Guidelines.

25. The Minister, in consultation with the Minister responsible for environment in Tanzania, shall not issue a permit to export Genetically Modified Organisms and, or products thereof that are banned by the laws of the importing country.

Prohibition of exportation.

26. (1) The Minister may revoke a permit where:

Revocation of a permit.

- (a) there is new evidence-based information by a recognized scientific body about the Genetically Modified Organisms activity and, or products thereof that demonstrate significant risk to human and animal health, environment and biodiversity;
- (b) there is breach of condition of the permit that may cause harm to the human and animal health, environment and biodiversity that cannot be satisfactorily mitigated;

- (c) it is discovered that the applicant made a misleading information or falsified documentation during the application process;
- (d) the continued operation of the Genetically Modified Organisms activity is causing damage or creates imminent threat of damage or loss; or
- (e) the permit holder failed to immediately notify the Focal Point where new information becomes available on the possible adverse risks to human and animal health, biodiversity or the environment after the permit has been issued.

(2) The Minister shall, before revocation of a permit notify a permit holder a notice to revoke a permit issued in order to give a chance to a permit holder to provide his defense where applicable.

Conditions
if the permit
is revoked.

27.-(1) Where a permit is revoked, the Minister may where applicable:

- (a) order to the responsible authority to destruct or sterilize of any growing Genetically Modified Organisms at the cost of the permit holder;
- (b) order to the responsible authority to destruct or repatriate the consignment of Genetically Modified Organisms and, or products thereof imported back to its country of origin at the cost of the permit holder; and
- (c) issue stop order to the permit holder for ongoing contained or confined research of Genetically Modified Organisms at the cost of permit holder.

(2) There shall be no compensation payable as a consequence of the revocation of a permit.

PART FOUR RISK MANAGEMENT

28. A permit holder shall, within fortyeight hours of any accident affecting biosafety levels, inform the Focal Point on the accident which shall include the following information: Notification of accident.

- (a) the circumstances of the accident;
- (b) the identity and quantity of the organisms or products involved;
- (c) measures necessary to assess the effects of the accident on human and animal health, environment and biodiversity; and
- (d) the emergency measures taken or intended to be taken.

29.-(1) The Focal Point shall direct the Authority to impose such measures as may be necessary to prevent adverse effects of the Genetically Modified Organisms and, or products thereof on human or animal health, biodiversity or the environment and taking into account socio-economic, cultural and ethical concerns. Measures to prevent adverse effects.

(2) Without prejudice to the provisions of subregulation (1) of this regulation, preventive measures may include the following:

- (a) order the suspension of any activity that is being undertaken in violation of any of the provisions of these Regulations;
- (b) require the person responsible for any activity to take measures necessary to prevent or limit any harm or damage and to restore the damaged environment to its previous state as far as possible;

- (c) the Authority shall take necessary measures to recover costs incurred from the responsible person if a permit holder failed to take such action; and
- (d) the Authority shall request a permit holder to submit periodic report on monitoring and evaluation of risks posed by the Genetically Modified Organisms activity.

(3) The Authority may advise the Focal Point to prohibit the Genetically Modified Organisms activity where it is proven that it contains characteristics or specific traits which pose risks to human and animal health, environment and biodiversity.

Emergency
plan.

30.-(1) A permit holder shall be required to have an emergency plan before conducting any Genetically Modified Organisms activity and shall submit that plan to the Authority for approval

(2) Subject to provisions of subregulation (1) of this regulation, the emergency plan shall address safety measures and procedures to be taken in case of an accident or unforeseen circumstances according to the Emergency Measures Response Manual.

PART FIVE MEASURES OF HANDLING GENETICALLY MODIFIED ORGANISMS

Require-
ments of
handling
Genetically
Modified
Organisms
and, or
products
thereof.

31.-(1) A permit holder shall be required to handle the Genetically Modified Organisms and, or products thereof under the conditions of biosafety as prescribed under the guidelines.

(2) A permit holder shall ensure that the consignment of Genetically Modified Organisms and, or products thereof to be imported or exported is clearly packed and labelled to indicate that the consignment is of Genetically Modified Organisms and, or products thereof.

(3) All applications shall be handled as per the procedures for handling Genetically Modified Organism activities as prescribed under Genetically Modified Organism Activities guidelines.

32. A permit holder shall take sufficient measures to comply with provisions governing the transportation of Genetically Modified Organisms and, or products thereof which includes:

Transportation of Genetically Modified Organisms.

- (a) preventing escape of Genetically Modified Organisms, so that they are not allowed to cross breed with domesticated indigenous organism;
- (b) proper identification and ensure it reach to the intended destination; and
- (c) ensure that the whole process is supervised by a competent authority under the cost of permit holder.

33.-(1) A permit holder who import, export or transit Genetically Modified Organisms and, or products thereof shall ensure that:

Compliance with National and International standards.

- (a) the PreInformed Consent is submitted to the Focal Point before starting the process of transportation;
- (b) the consignment is put in durable locked container enclosed in Primary, Secondary and Tertiary containers which are clearly labelled and sealed to avoid leakage and escape;
- (c) the consignment includes the address of sender and recipient;
- (d) the equipment used is cleaned after the transportation; and
- (e) the number of containers transported are the same upon delivery.

(2) Subject to the provisions of subregulation (1) of this regulation, a permit holder who imports, exports or transits of Genetically Modified Organisms and, or products thereof, shall contact the Focal Point for directives related to the container approved by transportation companies.

(3) The presentation of the Pre Informed Consent by the permit holder shall not exempt him from complying with any other applicable laws.

(4) Without prejudice to the provisions of these Regulations, the permit holder who intends to sale, export, import or transit of Genetically Modified Organisms and, or products thereof shall comply with any other relevant laws.

(5) The Minister may consult the minister responsible for environment of Tanzania in the issue of exportation, importation and transit of Genetically Modified Organisms and, or products thereof.

Conditions
for trans-
shipment
and transit.

34. A permit holder who transships or transit Genetically Modified Organisms and, or product thereof shall ensure that it is not consumed or planted in Zanzibar.

Genetically
Modified
food and
feed Aid.

35.-(1) Genetically modified food and feed Aid imported or transited into the Zanzibar shall comply with all conditions for importation prescribed under these Regulations.

(2) Subject to the provisions of subregulation (1) of this regulation, food and feed consignment involving grain that contain Genetically Modified Organisms that are imported or in transit shall be milled before distributed to the beneficiaries or transited.

PART SIX LIABILITY AND REDRESS

Liability for
Genetically
Modified
Organism
activities.

36.-(1) A permit holder whose Genetically Modified Organisms activity and, or product thereof has been proven to cause damage to

human and animal health, environment and biodiversity, shall be held liable for the damage that has occurred and shall pay compensation.

(2) For the purpose of this regulation, the term:

(a) damage includes:

- (i) personal injury;
- (ii) loss of property;
- (iii) financial or economic loss;
- (iv) environmental harm;
- (v) loss of biodiversity;
- (vi) loss of natural resources; or
- (vii) harm to public interest.

(b) compensation includes cost of:

- (i) rehabilitation;
- (ii) preventive measures;
- (iii) restoration;
- (iv) clean up measures;
- (v) economic losses; and
- (vi) personal injuries.

(3) A person who claim for compensation as a result of Genetically Modified Organisms activities and, or products thereof may lodge his claim through fault-based liability.

(4) A person who intends to institute a suit for damage and compensation under these Regulations shall be required to establish a causal link between the damage and the Genetically Modified Organisms activity and, or products thereof.

Defense.

37. A person shall not be held liable under regulation 36 of these Regulations if the damage was caused by Force Majeure.

Limitation
to liability.

38. The right to bring any action to redress the damage caused by the Genetically Modified Organisms activities and, or products thereof shall lapse only after reasonable period from the date on which the affected person or community could be expected to have knowledge of the damage taking account of:

- (a) the time the damage manifested itself; and
- (b) the time that it may take to relate the cause of the identified harm previously none-existent with the Genetically Modified Organisms activities and, or products thereof.

Damage
response
measures.

39.-(1) Without prejudice any provisions of these Regulations, where damage occurs and comes to the knowledge of the person in control of the Genetically Modified Organism activity and, or products thereof shall:

- (a) inform the Focal Point as soon as possible;
- (b) evaluate the damage; and
- (c) take appropriate response measures as warranted.

(2) Where it comes to the knowledge of the Focal Point that Genetically Modified Organisms activities and, or products thereof have caused damage, it shall:

- (a) identify the person that caused the damage;

- (b) cause to evaluate the damage;
- (c) determine which response measures to be taken by the person that caused the damage,
- (d) order the person to undertake response measures by his own cost.

PART SEVEN OFFENCES AND PENALTIES

40. A person who:

Offences
and penal-
ties.

- (a) undertakes any Genetically Modified Organism activities without a permit;
- (b) willfully neglects or intentionally violates any conditions attached to the permit issued under these Regulations;
- (c) import or transits Genetically Modified Organisms and, or products thereof without the Pre Informed Consent of the importing country;
- (d) willfully contravene the Genetically Modified Organisms the standards and, or products thereof;
- (e) violates any condition imposed under these Regulations,

commits an offence and shall, upon conviction, be liable to a fine of not less than Three Million Tanzanian Shillings but not exceeding Thirty Million Tanzanian Shillings or to imprisonment for a term not less one year and not exceeding seven years or to both fine and imprisonment.

41. A person who repeatedly commits an offence under these Regulations, upon conviction, the court may prohibit the offender from engaging in any activity in relation to Genetically Modified Organisms.

Repeated
offender.

Addition
penalty.

42. Upon convicting any person of any offence under these Regulations, the Court shall, in addition to any penalty, order:

- (a) repatriation of the consignment to the country of the origin by his cost;
- (b) to pay compensation equivalent to the value of damage caused to the affected person; or
- (c) restoration of the affected areas.

PART EIGHT MISCELLANIOUS PROVISIONS

Record
keeping and
repo Record
keeping and
reporting
ting.

43.-(1) The permit holder shall:

- (a) keep record of the performance of the permitted activity and all related activities; and
- (b) submit semi-annual reports on the conduct of the permitted activity to the Focal Point within thirty days upon receiving a permit following the lapse of the respective period.

(2) Where special reporting procedures are prescribed as a condition of a permit, such procedures shall be considered on submission of semi-annual reports under subregulation (1) of this regulation.

Register.

44. The Focal Point shall establish and maintain a register of all of application and permits issued under these Regulations.

Low
Level of
presence of
Genetically
Modified
Organisms.

45.-(1) The Focal Point shall put in place appropriate low-level presence of Genetically Modified Organisms that are contained in non-Genetically Modified Organisms imported for commercialization as direct use for food, feed and processing.

(2) Notwithstanding the provisions of sub regulation (1) of this regulation the Focal Point shall set threshold of level of five percent for imports of grain for food, feed and processing.

46.-(1) The Focal Point shall protect the received information which has been identified by applicant as confidential except by the order of the court.

Confidential business information.

(2) The Focal Point may, after issuing written notification to the applicant make confidential information available to the public.

(3) Where the applicant withdraws the application before it has been approved, the information provided shall remain confidential.

47. A permit holder who is carrying out Genetically Modified Organisms activities, shall upon request, submit to the Focal Point information that shall be necessary for carrying out functions under these Regulations.

Duty to disclose information.

48. The materials used for research shall be disposed in accordance with guidelines.

Disposal of material.

49. The Minister may make guidelines for the better implementation of these Regulations.

Guidelines.

FIRST SCHEDULE**[Made under regulation 14 (2)]
INTEREST DECLARATION FORM**

I....., member of the Technical Committee, declare the interest on the issue under the discussion, therefore I withdraw myself from discussion of the matter and decision making to avoid biasness.

.....

Name of the member

Date.....

I....., Chairperson of the, declare to receive interest declaration form from the member.

.....

Name of the Chairperson

Date.....

SECOND SCHEDULE

APPLICATION FORM FOR IMPORTATION, EXPORTATION, OR TRANSIT OF GENETICALLY MODIFIED ORGANISMS AND OR PRODUCT THEREOFF

[Made under regulation 15(1)]

Instructions

1. This application form consists of five parts which must be completed for any type of genetically modified organisms or products thereof exported, imported or transit from or into Zanzibar.
2. All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.
3. Please produce five copies of the application.
5. If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.
6. The Application must be submitted with proof of payment of the prescribed application fee.
7. Applications must be submitted 30 days prior to the exportation, importation or transit of the GMO.
7. Applications must be sent to the Principal Secretary at the address shown below.

**Principal Secretary,
The First Vice President's Office,
93 Julius Nyerere Road
P.O. Box 2808,
70460 Urban West Region
Zanzibar.
Email: Info@omkr.go.tz
Tel: +255(242232475)
www.omkr.go.tz**

PART 1	
INFORMATION OF THE APPLICANT	
Details of contact person	
Name:	
Address:	
P.O.BOX	
Street	
District	
Telephone	
Fax:	
EMAIL	
PART 2	
GENERAL INFORMATION	
Expected date of transit	
Expected date of exportation	
Expected date of importation	
Expected duration of transit	
Means of transportation	
Port of entry and exit	
Name of the recipient person	
Address:	
Street	
District	
Telephone	
Fax:	
EMAIL	
Fax:	
EMAIL	
PART 3	
INFORMATION ON THE IMPORTING COUNTRY	
Name of the country of importation/ imported	
State whether the transit requirements of the	

importing country have been complied.	
--	--

State whether an advanced informed agreement is needed before transit	
Information relating to storage before and during transit	
PART 4	
DESCRIPTION OF THE GMO	
Name of the GMO or product thereof	
Unique features of the GMO	
Information relating to its purposes and use	
Common and scientific names of the GMO	
Unique features of the modification	
Identity and function of the gene(s) responsible for the modified trait	
Organisms or tissues used in association with the GMO	
Quantity of the GMO or product thereof to be transited, imported or exported through Zanzibar	
If the GMOs to be transited, imported, or exported is in the form of grains, state whether or not they have been milled.	

PART 5:
DECLARATION AND SIGNATURES
I hereby declare and certify that the information in this application is complete and accurate to the best of my knowledge.
.....
SIGNATURE OF THE APPLICANT



APPLICATION FORM FOR CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS

Instructions

This application form consists of seven parts which must be completed for any type of research involving genetically modification under containment in Zanzibar.

All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Please provide 5 copies of the application for use by the Zanzibar Regulatory bodies.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

Please conduct a public notification in accordance Biosafety regulations of Zanzibar.

The appropriate fee as stipulated in the Zanzibar Biosafety Regulations must accompany the application. Please note that the First Vice president's office does not accept cash.

Applications must be received by Zanzibar Biosafety Focal Point (ZBFP) at the address shown below.

Principal Secretary,
The First Vice President's Office,
P.O. Box 2808, 93 Julius Nyerere Road, 70460
Zanzibar.
Email: Info@omkr.go.tz
Tel: +255(242232475)
www.omkr.go.tz

PART 1	
ADMINISTRATIVE INFORMATION	
Applicant	
Name of applying institution, including the name of the Principal Investigator or other key Personnel	
Name:	
Address:	
P.O.BOX	
Street	
District	
Telephone	
Fax:	
EMAIL	
Contact Details of Principal Investigator/Lead Scientist:	
Name of Lead Scientist	
Telephone (s):	
Address:	
Fax:	
E-mail	
Purpose of Application:	
Application for contained GM research (name of crop/animal species and introduced trait)	
Previous Applications or Approvals:	
Proposed Duration	
Expected starting date	
Expected terminated date:	
PART2: INFORMATION OF THE PROJECT	

Title of the project	
Proposed date of commencement of the project	
Proposed date of completion of the project	
Brief description of the project	

PART3	
DESCRIPTION OF GMO	
Name of the GMO or product thereof	
Common and scientific names of the GMO	
Vector (s) or method to be used for the transfer of the parent organism	
Indicate method of transformation, promoter, selection marker to be used	
Class of modified trait	
Identity and function of the gene(s) responsible for the modified trait	
Organism from which the gene(s) responsible for the modified trait(s) were isolated	
Organisms or tissues used in association with the GMO	
Organisms or tissues to be used in association with the GMO	
PART:4	
ADDITIONAL INFORMATION FOR A GMO THAT IS A WHOLE PLANT IN CONJUNCTION WITH A WHOLE PLANT	
Common and scientific names of the parent organism	
Weediness of the parent organism	
Stage of plant development to be grown	
Growing medium for the plants	
PART 5: RISK ASSESSMENT AND MANAGEMENT	
Health and safety of people	
Possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (<i>i.e.</i> the risk) from the proposed genetic modification(s)	

Possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (<i>i.e.</i> the risk) from an unintentional release of the GMO(s) into the environment?	
Kinds and level of notifiable risk dealing	
Transportation of the GMO(s) outside the contained facility	
Indicate if the transformed materials will be transported outside the contained facility and if so how	
Disposal of the GMO	
Description how the transformed materials will be disposed	
Other actions and precautions to be taken to minimise risks posed by the proposed dealing(s)	
Describe other safety measures will be put in place to minimize any potential risks	
PART 6: DESCRIPTION OF THE CONTAINMENT FACILITY	
Information of the facilities to be used	
Give brief description of the containment facility and provide sketch	
Facility type:	
Physical containment level:	
Address:	
Facility contact person details	
Name:	
Business phone number:	
Mobile phone number:	
Facsimile number	
E-mail address:	

Principal Investigator of the Applying Institution

Name:

Signature:

Date:

Project Supervisor

Name:

Signature

Date:



APPLICATION FOR CONFINED FIELD TRIAL OF GENETICALLY MODIFIED ORGANISMS

Instructions

This application form consists of seven parts which must be completed for each individual genetically modified plant species proposed for environmental release in a confined field trial in Zanzibar.

All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Please provide 5 copies of the application with confidential information for use by the Zanzibar regulatory bodies.

Please provide 5 copies of the application for use by the Zanzibar regulatory bodies.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

The appropriate fee as stipulated in the Zanzibar Biosafety regulations must accompany the application. Please note that the First Vice president's office does not accept cash.

Applications must be received by Zanzibar Biosafety Focal Point (ZBFP) at the address shown below.

Principal Secretary,
The First Vice President's Office,
P.O. Box 2808, 93 Julius Nyerere Road, 70460
Zanzibar.
Email: Info@omkr.go.tz
Tel: +255(242232475)
www.omkr.go.tz

1. Administrative Information

Applicant:

[Name of applying institution, which may also include the name of the Principal Investigator or other key personnel.]

Name of Institution:

Address:

P.O. Box:

Physical Address:

Street:

District

Town/City

Telephone (s):

Fax:

E-mail:

Contact Details of Principal Investigator/Lead Scientist:

Name of Lead Scientist:

Address:

Telephone (s):

Fax:

E-mail:

Purpose of Application:

[Application for a confined field trial for (name of crop species and introduced trait).]

Previous Applications or Approvals:

[Information on the status of this crop and trait, including pending, approved, or denied applications for field trials and commercial releases here or in other jurisdictions. Indicate also if this is a new application or a renewal.]

Proposed Location and Size of Trial:

[Name, address, email, phone, and facsimile of the Trial Manager as well as GPS information or description of the exact location and size of the trial site (attach sketch map).]

Proposed Duration of Trial:**Expected starting date:****Expected termination date:****2. Plant Information****2.1 Unmodified Plant Information**

This section describes the characteristics of the unmodified plant as it relates to confinement. Important information pertains to the plant's reproductive mechanisms and its ability to escape, establish, and persist in the environment into which it is being introduced.

Plant Species Name (common and scientific):**Centre of Origin:**

[What is the centre of origin of the unmodified plant?]

Reproductive Mechanism of the Plant:

[Describe the reproductive biology of the plant. This information may be obtained from Organization for Economic Co-Operation and Development (OECD) biology consensus documents or similar sources, and should include relevant information on: inter- and intra-specific breeding; pollen production, dispersal, and viability; seed production and dispersal; seed dormancy; capacity for vegetative reproduction.]

Tendency to Weediness:

[Is the unmodified plant regarded by agricultural experts as a weed in Tanzania or elsewhere? If so, are control methods available that may be used to effectively limit the dispersal and establishment of the unmodified plant? NOTE: The information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this application.]

Toxicity and Allergenicity:

[Is the plant species known to be a source of substances that are toxic or allergenic to humans or animals? If yes, identify the substances and levels that induce toxicity or allergenicity and the affected species.]

Allelopathy:

[Is the plant species known to be allelopathic? If yes, give details]

2.2 Modified Plant Information

This section is intended to provide information on known or intended effects of the genetic modification or introduced trait that may affect confinement measures employed in the confined trial.

Describe the Intended Phenotypic Changes to the Plant:**Intended Reproductive Effects:**

[Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes effect strategies for confinement?]

What is the source of the genetic material? Is the source of the genetic material likely to affect the safe conduct of a confined field trial? If yes, how?

[Describe any known or intended introduction of infectious agents, plant, animal or human pathogens or allergens or toxins.]

Changes in Toxicity or Plant Composition:

[Describe any changes to toxicity, allergenicity, or significant changes in composition intended by the genetic modification.]

Describe the Features of the Genetic Construct:

[Include coding sequences, promoters, enhancers, termination, and polydenylation signal sequences. Attach a genetic map and describe the method of modification in an annex.]

Stable Integration of the Inserted DNA:

Indicate the site of Integration of the Introduced DNA

Indicate how stable integration of the DNA was demonstrated

Expression Products of the Introduced Gene(s):

Provide information for each protein product of the introduced gene(s) - maximum level of expression in the edible portions of the plant, whether the protein known to be allergen or toxic to humans or animals

3. Trial Description

This section describes the purpose of the field trial, anticipated planting and harvesting dates, the experimental design and data to be collected, including anticipated use of pesticides, fertilizers and any agro-chemicals. Include a description of the habitat at the site, and any organisms of conservation concern that may be in the general area.

Trial Description:**4. Genetic Confinement**

This section describes the measures to be taken to ensure confinement of the genetically modified plants and genes. It is based on knowledge of the unmodified crop and the intended genetic modification.

Provide a map showing the location of the trial site, surrounding fields, and relevant geographic features such as streams or waterways.

Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting in viable seeds?

Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial site:

[Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and/or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology.]

Describe measures in place to control trial plant volunteers after termination of the trial:

[Describe the crops to be allowed following the confined trial, duration of monitoring for volunteers, frequency of monitoring, methods of destruction and disposal of any identified volunteers, and any other measures needed to ensure that the trial plants do not persist on the trial site.]

5. Material Confinement

This section describes the mechanisms by which trial personnel will maintain control of the genetically modified plant material, so that it is not mixed with non-modified plant material, does not escape into the environment, and is not eaten by humans or livestock.

Packaging:

[Describe how the genetically modified plant material will be packaged and labelled for transport to the trial site and measures for cleaning and/or disposing of the packaging material. Note that the chain of custody documentation is required for all genetically modified material being transported.]

Harvesting, Transport, and Storage:

[Describe how the plant material will be harvested, including plans for any material to be retained, and how that material will be stored and/or transported.]

Disposal and Clean-Up:

[Describe how surplus planting material will be disposed of at the trial site, how any equipment used during planting or other farm operations will be cleaned, and how harvested materials and crop residues will be disposed.]

Site Security:

[Describe measures in place to ensure security of the trial site to prevent incursion by humans or animals. Measures may include fencing, security patrols, lockable gates, etc...]

6. Records, Personnel, and Planning

Records and Documentation:

[Describe measures in place to ensure adequate documentation of all confinement measures and data requirements as described herein.]

Contact Details of Site Manager:

Name of Site Manager:

Address:

Telephone (s):

Fax:

E-mail:

Personnel:

[Briefly describe competence of the Site Manager and measures in place to ensure that trial personnel will have appropriate education, experience, and training to adequately perform assigned duties for confinement and technical requirements of the trial.]

Contingency Plans:

[Describe planned response to the loss of control or accidental release of genetically modified plant material, including notification of authorities and the Authorized Party, recovery and disposal of plant material, and any other measures to be taken to mitigate any potential adverse effects.]

Part 7: Declaration and Signatures

I hereby declare and certify that the information in this application is complete and accurate to the best of my knowledge and belief.

Principal Investigator of the Applying Institution

Name:

Signature:

Date:

Project Supervisor

Name:

Signature

Date:



APPLICATION FORM FOR COMMERCIALIZATION OF GENETICALLY MODIFIED ORGANISMS INTO ZANZIBAR

Instructions

This application form consists of seven parts which must be completed for each individual genetically modified plant species proposed for environmental release in a confined field trial in Zanzibar.

All sections of this application must be clearly completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Please provide 5 copies of the application for use by the Zanzibar regulatory bodies.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted.

Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.

Please provide an electronic and hard copy of a risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed below.

Please conduct a public notification in accordance Biosafety regulations of Zanzibar.

The appropriate fee as stipulated in the Zanzibar Biosafety regulations must accompany the application. Please note that the First Vice president's office does not accept cash

Applications must be received by Zanzibar Biosafety Focal Point (ZBFP) at the address shown below.

Principal Secretary,
The First Vice President's Office,
P.O. Box 2808, 93 Julius Nyerere Road, 70460
Zanzibar.
Email: Info@omkr.go.tz
Tel: +255(242232475)
www.omkr.go.tz

PART I

1. BRIEF DESCRIPTION OF THE GENETRICALLY MODIFIED PLANT

Include specific and common names of the plant, the country of origin of the plant and a description of the genetically modified trait.

2. GENERAL RELEASE

Detail specific instructions for the storage and handling of the plant, or viable plant parts.

When will general release be implemented?

Where will general release take place?

Detail the type of environment and the geographical areas for which the plant suited.

Who will undertake the general release?

Estimate the amount of production of the genetically modified plant within Tanzania per annum, or the amount of viable plant product to be imported into Tanzania per annum.

3. DESCRIPTION OF ANY PRODUCT DERIVED FROM THE PLANT

Identify the part of the plant to be used for the product, the type of product, and the use of the product, the market sector in which the product will be marketed and the trade name of the product.

Specify the exact conditions of use of the product.

Provide information on the proposed labeling of the product for marketing.

State whether the benefits of the product are available in any other non-genetically modified form. If so, state why the genetically modified form should be approved for general release when other, non-modified products are available.

Details specific instructions for the storage and handling of viable plant products that will avoid misuse or escape of the genetically modified plant into an environment for which it was not intended.

Detail the likelihood of the genetically modified plant or its products being exported from Tanzania, particularly if such export could result in the introduction of the plant into its centre of origin.

4. BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN

Submit a list of previously authorized activities with the GMO in

- (a) Tanzania Mainland
- (b) East Africa
- (c) Tanzania Zanzibar
- (d) Other countries

Include information on the country, year, location and the authority from which permission was obtained to run the field trials.

Provide full data on the field performance of the genetically modified plant, including the efficacy of the introduced trait.

5. POLLEN SPREAD

Identify all methods of pollination applicable to the plant.

Identify pollinating agents and the distances to which pollen is known to spread.

Identify any plants in the area of general release that may become cross-pollinated with the genetically modified pollen.

Describe methods to be used to prevent the spread of genetically modified pollen to wild type plants.

6. SEED DISPERSAL

If seed to be sold, state whether the seed is hybrid.

Describe methods to be used to limit the dispersal of genetically modified seed into the environment.

If seed dispersal will occur describe what volumes of seed are likely to be dispersed, how this seed will interact in the environment and what long-term effects the seed is likely to have on the environment.

7. VEGETATIVE SPREAD OF THE GENETICALLY MODIFIED PLANTS

Describe methods of vegetative reproduction that are available to the plant.

Describe methods to be used to limit vegetative spread of the genetically modified plant into the environment.

8. FOREIGN GENES AND GENE PRODUCTS

Identify all foreign genes in the genetically modified plant.

Describe the gene products that are derived from the foreign genes.

Describe the biological activity associated with the foreign gene products.

Provide information on the rate and level of expression of the foreign genes and the sensitivity of the measurement of the rate and level. State whether expression is constitutive or inducible. Are foreign genes expressed throughout the plant or only in certain organs or tissues?

Provide protocols for the detection of the foreign genes in the environment including sensitivity, reliability and specificity of the techniques.

9. RESISTANCE

Detail whether the genetically engineered plant is able to initiate resistance, in any biotic component of the environment, to any biologically active foreign gene product.

Detail what methods are available to minimize the risk of resistance developing in the environment.

Detail how resistance will be managed during general release of the genetically modified plant.

10. HUMAN AND ANIMAL HEALTH

Please take cognizance of the requirements pertaining for food and feed safety, as contained in the guidelines for use of GMO's. You are required to follow these guidelines in compiling the information for your application.

State whether the genetically modified plant or its products will enter human or animal food chains.

Detail the results of experiments undertaken to determine the toxicity of the foreign gene products (including marker genes) to humans and animals.

If the foreign gene products are toxic or allergic in any way, detail how the general release will be managed to prevent contact with animals or humans that will lead to discomfort or toxicity.

What are the implications of the proposed activity with regard to the health and safety of the workers, cleaning personnel and any other person that will be directly or indirectly involved in the activity? Please take into consideration the provisions of the Occupational Health Safety Act, Cap. 297 accompanied regulations.

Further to the question raised above, indicate the proposed health and safety measures that would be applied to safeguard employees during the proposed activity.

11. ENVIRONMENTAL IMPACT AND PROTECTION

Detail any long-term effect the general release of the genetically modified plant is likely to have on the biotic and abiotic components of the environment.

Provide data and information on ecosystems that could be affected by use of the plant or its products.

Specify what effect the general release of the genetically modified plant will have on biodiversity.

Specify the measures to be taken in the event of the plant or product being misused or escaping into an environment for which it is not intended.

If the foreign genes give rise to crops resistant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.

12. SOCIO-ECONOMIC IMPACTS

Specify what, if any, positive or negative socio-economic impacts the genetically modified plant will have on communities in the proposed region of release.

13. MONITORING AND ACCIDENTS

Indicate the methods and plans for monitoring of the GMO

Indicate any emergency procedures that will be applied in the event of an accident.

14. PATHOGENIC AND ECOLOGICAL IMPACTS

Submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts.

15. WASTE DISPOSAL

Where only a portion of the genetically modified plant will be used for the product, how will the unused plant parts be disposed of?

16. RISK MANAGEMENT

Please indicate any risk management measures that would be required during the trial.

17. COMPLETE THE AFFIDAVIT.

The affidavit is an inseparable part of the application form.

THIRD SCHEDULE FEES AND CHARGES

[Made under regulation 15(2) and 19 (4)]

S/N	DESCRIPTION	CURRENCY TSH	AMOUNT TSH	USD
1.	Application fee for:			
	Every application shall be accompanied by a non-refundable scrutiny fee			
	developing GMO or products thereof	TSH	500,000	200
	importing Regulated GMO or products thereof	TSH	1,000,000	425
	exporting GMO or products thereof	TSH	1,000,000	425
	transiting GMO or products thereof	TSH	500,000	200
	undertaking contained research (Tanzanian)	TSH	500,000	200
	undertaking contained research (Foreigner)	USD	1,000	
	undertaking confined field research (Tanzanian)	TSH	500,000	200
	undertaking confined field research (Foreigner)	USD	1,000	
	undertaking on farm research	TSH	500,000	200
	undertaking on farm trial (Foreigner)	USD	1,000	
	Commercialization	TSH	1,000,000	425

	GMO or products thereof			
	Commercialization GMO or products thereof	USD	3000	
2.	Review and evaluation of risk assessment fee for:			
	importing Regulated GMO or products thereof	TSH	10,000,000	4250
	exporting GMO or products thereof	TSH	2,000,000	850
	transiting GMO or products thereof	TSH	2,000,000	850
	undertaking contained research (Tanzanian)	TSH	5,000,000	210
	undertaking contained research (Foreigner)	USD	10,000	
	undertaking confined research (Tanzanian)	TSH	5,000,000	2100
	undertaking confined research (Foreigner)	USD	10,000	
	Commercialization GMO or products thereof	TSH	10,000,000	4250
3.	Costs for permit	Tsh	500,000	200

FOURTH SCHEDULE

PERMIT FOR A GENETICALLY MODIFIED ACTIVITIES

[Made under regulation 23(2)]

PERMIT FOR GENETICALLY MODIFIED ORGANISM ACTIVITIES

[Insert date]

1. Applicant Information:

Name of Applicant: [Insert name of organization/individual] Address: [Insert complete address] Contact Details: [Insert phone number and email address]

2. GMO Information:

Name of GMO: [Insert name of GMO] Intended Use of GMO: [Insert intended use of Genetically Modified Organisms] Description of GMO: [Insert a brief description of the GMO, including its characteristics, genetic modification]

3. Research and Application Details:

Location of Research and Application: [Insert complete address of the research and application site] Duration of Research and Application: [Insert start and end dates of the research and application] Method of Containment: [Insert the method of containment used]

4. Permit Conditions:

The following conditions must be met during the research and application of the GMO together with detail Terms and Conditions issued in a separate document:

- The research and application must be conducted in accordance with the applicable laws and regulations.
- The method of containment must be appropriate and effective in preventing the spread of the GMO.

- The applicant must implement appropriate monitoring and emergency response procedures in case of any unforeseen incidents as per the applicable Guidelines and the Standard Operating Procedures (SOPs).
- The applicant must submit regular progress reports to the regulatory agency.
- The applicant must ensure that any waste or byproducts generated during the research and application are properly disposed of in accordance with the applicable laws, regulations and Standard Operating Procedures (SOPs).
- The applicant must obtain all necessary permits and approvals from relevant authorities before conducting any field trials or commercial releases.

5. Acknowledgement and Signature:

I, [Insert name of applicant], acknowledge that I have read and understand the conditions of this permit for GMO research and application. I agree to comply with all the conditions set forth in this permit.

SIGNED on this 16th day of August, 2024

.....
HON. HARUSI SAID SULEIMAN
MINISTER OF STATE, FIRST VICE PRESIDENT'S OFFICE
ZANZIBAR