Manual on Procedures for Handling Requests or Applications of Genetically Modified Organisms (GMOs) in Tanzania

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For further information, please contact:
Permanent Secretary,
Vice President's Office,
P. O. Box 5380,
Dar es Salaam.
TANZANIA.
Phone: +255-22-2113983
Fax: +255-22-2125297
E-mail: biosafety@vpdoe.go.tz

PREFACE

To date, more than one hundred varieties of Genetically Modified Organisms (GMOs) have been developed and approved for commercialization for use as food or crops worldwide. In this regard, Tanzania has already put in place regulatory framework so as to ensure safe transfer, handling and use of modern biotechnology. However, the challenge lies with strengthening enforcement capacity of the relevant Regulatory Authorities. Therefore, building capacity of the Regulatory Authorities is a priority in order to facilitate effective and informed decision making with regard to GMOs and their product thereof.

This Manual has been developed to serve as a guide for handling requests or applications of Genetically Modified Organisms (GMOs). It is meant to facilitate adherence to administrative and legal instruments in reviewing and approving applications, and monitoring of contained research, confined field trial and commercial release of GMOs (specifically for plants released in the environment). Guidelines for commercial release of other GMO applications including animal, microbes and fish will be prepared later.

The Manual outlines the procedures and steps to be followed by Applicant who arranges to be involved in research and development, handling, transit, contained use, trans-boundary movement, release or placing on the market of GMOs whether intended for release into the environment, for use as food, feed or processing. It should be noted that the Manual will be reviewed periodically to accommodate emerging issues related to safe transfer, handling and use of modern biotechnology. It is anticipated that the Manual will be useful to its many users.

Dr. Batilda Salha Burian (MP)
Minister of State - Environment
Vice President's Office

ACKNOWLEDGEMENT

The successful preparation of this Manual is a result of joint efforts of several experts and institutions that deserve a vote of appreciation. Due to space limitation, we cannot mention all of them. However, we assure them of our heartfelt appreciation and that we value their cooperation and support.

We are deeply indebted to the team of experts that compiled and edited this Manual for their commendable efforts and inputs. The team comprised Dr. S. R. Mwinjaka, Dr. C.M. Shayo, Mr. F. Ngerageza, Mr. S. Nkondokaya, Mr. O. Kamukuru, and Mr. T. Bwana from the Vice President's Office; Dr. A. Kullaya and Dr. E. Mneney from Mikocheni Agricultural Research Institute (MARI); and Dr. Roshan Abdallah from Tropical Pesticides Research Institute (TPRI).

We are also thankful to Mr. E. K. Mugurusi, former Director of Environment, who provided overall guidance and coordination of the process.

Last but not least, we are grateful to UNEP-GEF for providing financial support to accomplish this task. We are particularly indebted to Mr. Alex-Owusu Biney, UNEP-GEF Biosafety Regional Manager for Africa, in reviewing the Manual.

Ruth H. Mollel
Permanent Secretary
VICE PRESIDENT'S OFFICE

CONTENTS

ACRONYMS

AIA	Advance Informed Agreement
CBI	Confidential Business Information
CHM	Clearing House Mechanisms
CV	Curriculum Vitae
DNA	Deoxyribonucleic Acid
ERA	Environmental Risk Assessment
GM	Genetically Modified
GMO	Genetically Modified Organism
GPS	Global Positioning System
IBC	Institutional Biosafety Committee
MCA	Ministerial Competent Authority
NBFP	National Biosafety Focal Point
OECD	Organization for Economic Co-Operation and Development
PI	Principle Investigator
URT	United Republic of Tanzania

LIST OF REGISTERS

LIST OF FORMS

1.0 INTRODUCTION

The National Biosafety Framework requires that all types of activities involving genetically modified organisms (GMOs) require a permit from a competent authority. This manual on procedures for handling requests of GMOs in Tanzania is based on the national biosafety framework which takes its legal mandate from the Biosafety Regulations (2009), the administrative system for risk assessment and decision making and the biosafety guidelines. It is intended to guide the different authorities responsible for handling requests for a permit to conduct an activity involving genetically modified organisms in Tanzania.

2.0 SUBMISSION AND HANDLING OF REQUESTS OR APPLICATIONS BY THE NATIONAL BIOSAFETY FOCAL POINT (NBFP)

The Applicant has to submit the application to the NBFP at least 6 months (180 days) prior to the start of the intended GMO activity. The application should be submitted by regular mail or courier delivery to the NBFP through the following address:

Permanent Secretary
Vice President's Office
P. O. Box 5380
Dar es Salaam
TANZANIA

Upon receipt of the application, the NBFP will stamp the date of receipt, enter it in its register/database, assign a tracking number and acknowledge receipt within two (2) weeks. To be able to track and document the status of the review process, the NBFP will fill in a tracking record sheet (Form B) and attach it to the application as it is sent to the different Authorities for review. This tracking record sheet should to be signed by each relevant Authority involved in the review process. It is also important for the NBFP to keep a register (as hard copy and e-database) showing the list of submitted applications, date received, when and what action was taken and by whom, as detailed in Register 1.

Register 1: List of Biosafety Applications at NBFP

Serial Nr.	Tracking Nr	Date Received	Receiving Officer	Name of Applicant	Type of Application	Action*)	Date of Action	Dispatching Officer

*) 1 = forwarded to MCA for scientific review
2 = Sent back to Applicant

The records and tracking numbers shall be kept in a simple electronic database so that the information can be made readily available both within the government and to various stakeholders. An electronic database enables the information to be easily searched, and it can be integrated into other aspects of providing information.

Once a request has been properly recorded, the request is screened for completeness, i.e. whether it complies with the procedural and information requirements as per checklist for screening biosafety applications (Form A of this manual).

In case the application does not fulfill the information requirements, the NBFP will ask the applicant to provide additional information. For reasons of transparency and efficiency, the request for additional information will be done in writing, and will be as specific as possible. Each request for additional information will be clearly justified and the timeframe for response will be specified depending on the nature of the missing information.

If it is concluded that the request is in compliance with the procedural and information requirements, the NBFP will, within fourteen (14) days, forward it to the respective Ministerial Competent Authority (MCA) for scientific review. At the same time, the NBFP will inform the applicant accordingly and will make a public announcement of the request and post it to its Clearing House Mechanism (CHM) at www.vpo.go.tz/bch/index.php. It is

important to note that in making the announcement, the NBFP will not reveal to the public any confidential business information.

3.0 THE REVIEW PROCESS

According to the National Biosafety Guidelines for Tanzania (2007), the Applicant shall submit his/her biosafety application to the National Biosafety Focal Point (NBFP), currently the Ministry responsible for Environment. Where applicable, the applicant is advised to establish informal consultation with relevant regulatory authorities, such as MCA, IBC and Biosafety Offices, to ensure that the request contains the required information.

The NBFP shall then forward the application to the relevant Ministerial Competent Authority (MCA) for review by its relevant Committees. After the review, the MCA will give its recommendations to the NBFP, which in turn, will request the National Biosafety Committee (NBC) to conduct further review. The NBC shall then make its recommendations and appropriately advise the Minister responsible for Environment. The decision of the Minister will then be communicated to the applicant by NBFP. The timeline for each review process has been specified in the next sections.

3.1 Ministerial Competent Authority (MCA)

When the application is received, the Ministerial Competent Authority (MCA) will stamp the date of receipt on the tracking record sheet attached by the NBFP (Form B). The MCA will also keep a register (as hard copy and e-database) showing the list of submitted applications, date received, when and what action was taken and by whom, as detailed in Register 2.

Register 2: List of Biosafety Applications at MCA

Serial Nr.	Tracking Nr	Date Received	Receiving Officer	Name of Applicant	Type of Application	Date of Review	Date Sent to NBFP	Dispatching Officer

The MCA will then re-check if the application forms are complete. If the MCA is convinced that the application forms are complete, it will, within two (2) weeks from the receipt of the application, convene a meeting to review the application. This process should be completed within two (2) months. When the review process has been completed, the MCA will send the original copy of the application together with its recommendations to the NBFP. The MCA will record in its register (Register 2) the date of sending the application and its recommendations to the NBFP, and retain a copy of the documents in a safe locked cabinet. The recommendations will:

- Give a summary of the request or application;
- describe the procedure followed, including the solicitation of advise and comments;
- indicate results of the risk assessment carried out.

The recommendations will be documented in Form C.

3.2 Institutional Biosafety Committee (IBC)

When the request is submitted to the IBC from MCA, for review and/or consultation, the IBC will stamp a date and record in its register. The IBC will, within fourteen (14) working days of receipt of the application, to convene a meeting to scrutinize the application. The IBC will provide its recommendations within a period of fourteen (14) working days of the receipt of the application. If the recommendations of the IBC are positive, the applicant will then forward the application together with the recommendations to the NBFP.

3.3 National Biosafety Committee (NBC)

The Ministerial Competent Authority (MCA) will send its recommendations of the scientific review to the NBFP, which will stamp the date of receipt on the tracking record sheet. The NBFP will then, within five (5) working days, send the application and the recommendations of the MCA to the Chairperson of the National Biosafety Committee (NBC) and request to start a process of reviewing the application, taking into consideration the recommendations of the MCA. The review of applications for contained or confined research by the NBC should be completed within one (1) month. However, applications for general release could take up to two hundred and seventy (270) days because of the need to consult the public and other stakeholders.

The NBC will record in its register (Register 3) the date of sending the application and its recommendations to the Minister. The NBC, like the other Authorities, will also keep a register (as hard copy and e-database) showing the list of submitted applications, date received, when and what action was taken and by whom, as detailed in Register 3.

Register 3: List of Reviewed Biosafety Applications by the NBC

Serial Nr.	Tracking Nr	Date Received	Receiving Officer	Name of Applicant	Type of Application	Date of Review	Date Sent for Decision	Date of Informing Applicant	Dispatching Officer

4.0 DECISION MAKING

When the review process has been completed (Figure 1), the NBFP, which is the NBC Secretariat, will, within two (2) weeks, prepare a decision document based on the recommendations of the NBC. The decision document will have the following structure:

- Summary of the request or application;
- Description of the procedure followed , including the solicitation of advise and comments;
- A presentation of risk assessment carried out;
- The final decision. The decision on the application can be to allow, with or without conditions, or to deny permit or approval for the requested activity.

The NBFP will then send the original copy of the application together with the decision document to the Minister Responsible for Environment for approval. The decision of the Minister will then be communicated to the applicant within ten (10) working days after the Minister has made the decision. The NBFP will also inform the respective IBC and MCA of the same so that they can get prepared for making follow up in case the application was approved.

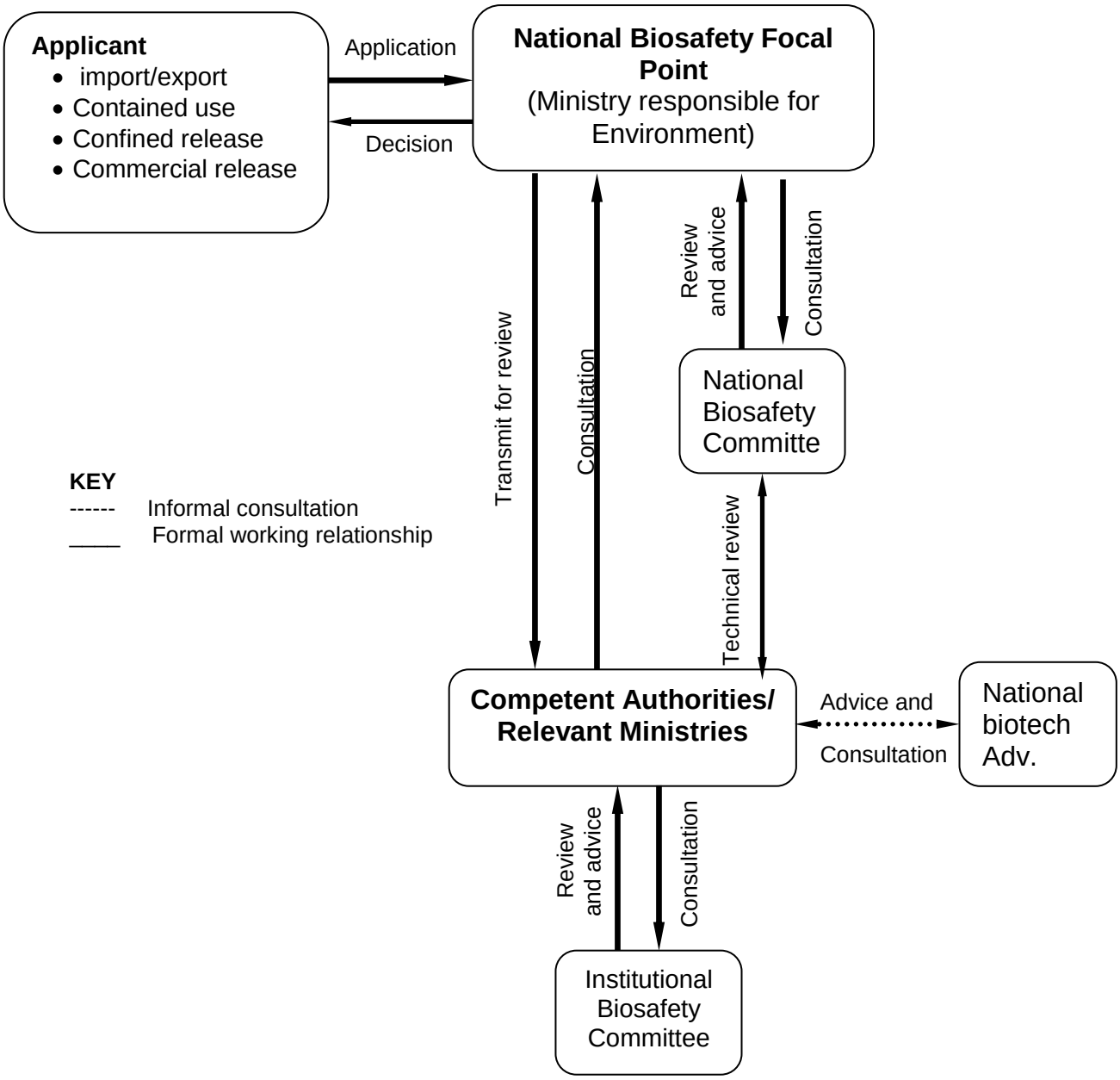

Figure 1: Decision making structure

5.0 MONITORING

After a permit has been given, the Regulatory Authorities of the respective MCA will start a monitoring mechanism in order to:

- ensure compliance with the provisions of the permit;
- gather information with a view to future assessments;

- survey for unintended impacts on human health and the environment; and
- be able to advise the NBC and NBFP accordingly.

6.0 MECHANISM FOR PUBLIC AWARENESS AND PARTICIPATION

The NBFP, Competent Authorities and other agencies should promote and facilitate public awareness, education and participation through the use of databases, the internet, and informal and formal consultation with stakeholders. Further examples include public hearings, conferences, demonstration projects, and public debates on biotechnology issues.

ANNEX: APPLICATION FORMS

:

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

FORM A: CHECKLIST FOR SCREENING BIOSAFETY APPLICATIONS AT NBFP

A.1 NAME OF APPLICANT	**A.2 TYPE OF APPLICATION** Γ New Γ Renewal Γ Supplementary
A.3 TITLE AND PURPOSE OF APPLICATION	
A.4 TYPE OF PROJECT Γ Contained Research Γ Confined Field Trial Γ Commercial release	**A.5 Date Received at NBFP** **A.6 Assigned Tracking Nr.**
A.7 Administrative Information **Is the Information Provided complete** Γ Yes Γ No If no, what is missing?	**A.8 Technical Information** **Is the Technical Information Provided Complete** Γ Yes Γ No If no, what is missing?

A.9 Other Important Information

- Has an advance informed agreement (AIA) from NBFP been sought Γ Yes Γ No
- Is the name and address of the place where the GMO activity will take place indicated? Γ Yes Γ No
- Has the applicant declared that the information submitted is correct Γ Yes Γ No

A10 DECISION TAKEN BY NBFP

Γ Accepted and forwarded to Respective MCA for Review on: ……

Γ Rejected and returned to Applicant for Improvement on ……

A11 RESPONSIBLE OFFICER

…… ……..…….. ……......

Name **Signature** **Date**

Designation: ……

UNITED REPUBLIC OF TANZANIA
MINISTRY OF …….
NAME OF MINISTERIAL COMPETENT AUTHORITY

FORM B: TRACKING RECORD SHEET FOR BIOSAFETY APPLICATIONS
(To be filled in by NBFP and attached to the application as it is sent to different Authorities for review)

B.1 NAME OF APPLICANT	**B.2 TYPE OF APPLICATION** Γ New Γ Renewal Γ Supplementary	
B.3 TITLE AND PURPOSE OF APPLICATION		
B.4 TYPE OF PROJECT Γ Contained Research Γ Confined Field Trial Γ Commercial release	**B.6 Tracking Nr. Assigned by NBFP**	
B.7 ACTION	Date	By Whom (Name and Signature)
Application Received by NBFP		
Application dispatched by NBFP to MCA		
Application received by MCA		
Dispatch of Recommendations of MCA to NBFP		
Recommendations of MCA received by NBFP		
Recommendations of MCA received by NBC		
Dispatch of Recommendations of NBC to NBFP		
Recommendations of NBC received by NBFP		
Decision by Minister		
Communication of Decision to the Applicant		

UNITED REPUBLIC OF TANZANIA
MINISTRY OF ……
NAME OF MINISTERIAL COMPETENT AUTHORITY

FORM C: RECOMMENDATION SHEET BY THE MCA

B.1 NAME OF APPLICANT	**B.2 TYPE OF APPLICATION** Γ New Γ Renewal Γ Supplementary
B.3 TITLE AND PURPOSE OF APPLICATION	
B.4 TYPE OF PROJECT Γ Contained Research Γ Confined Field Trial Γ Commercial release	**B.5 Date Received at MCA** **B.6 Tracking Nr. Assigned by NBFP**
B.7 RECOMMENDATION OF THE MCA • Summary of the request or application; • Description of the procedure followed, including the solicitation of advise and comments; • A presentation of risk assessment carried out; • Recommendation. • Include the relevant attachments	
B.8 SIGNED BY THE DESIGNATE OF THE MCA …… …….…… ……..... **Name** **Signature** **Date**	
B.9 DISPATCHED BY THE MCA TO NBFP …… …….…… ……..... **Name** **Signature** **Date**	

FORM D: APPLICATION FORM FOR CONTAINED GM RESEARCH IN TANZANIA

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

Γ **CBI COPY**
Γ **NO CBI**

General Instructions

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

All sections of this application must be 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.

Submit 5 copies of the application for use by the NBFP in both hard and soft forms by regular mail or courier delivery.

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.

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

Conduct a public notification in accordance to biosafety regulations of Tanzania

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

Applications must be received by national Biosafety Focal Pont (NBFP) at the address shown below at least **180 days in advance** of the commencement date of the proposed research.

Permanent Secretary
Vice President's Office
P.O. Box 5380
Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

PART 1: APPLICANT/ADMINISTRATIVE INFORMATION

Instructions

- *Name of applying institution, including the name of the Principal Investigator or other key personnel should be provided.*
- *Applicant should be a permanent resident of the United Republic of Tanzania (URT) or a designated agent who is permanent resident of URT*

1.1 Contact Details of Principal Investigator (PI)

Name of Principal Investigator (PI):

Postal address:

Physical Address:

Telephone:

Mobile phone:

Fax:

E-mail:

Attach:
- Current CV
- Name of and Contact of three referees

1.2 Name and address of the Institution:

Name of the Institution:

Postal Address:
P.O. Box:

Physical Address:
Street:
District:
Town/City

Telephone (s):

Cell Phone:

Fax:

E-mail:

Website:

1.3 Institutional Biosafety Committee (IBC)

Name of the IBC Chairperson Secretary Address: P.O. Box: Physical Address: Street: District: Town/City Telephone (s): Cell Phone: Fax: E-mail:

Title and Purpose of Application: Title Purpose

Previous Applications or Approvals

PART 2: INFORMATION ABOUT THE PROJECT

2.1 Title of the project

2.2 Proposed date of commencement of the project

2.3 Proposed date of completion of the project

2.4 Brief description of the project

PART 3: DESCRIPTION OF THE GMO

3.1 Common and scientific names of the parent organism

Common name: Scientific name(s):

3.2 Vector(s) or methods to be used for the transfer of genetic material

Indicate method of transformation; promoter, selection marker to be used

3.3 Class of the modified trait

E.g. Pest resistance, drought tolerance, disease resistance, Biofortification et.

3.4 Modified trait

E.g. Resistance to Bollworm, elevated Provitamin A etc.

3.5 Identity and function of the gene(s) responsible for the modified trait

E.g. Resistance to Bollworm, elevated Provitamin A etc.

3.6 Organism (s) from which the gene(s) responsible for the modified trait(s) were isolated

3.7 Organisms or tissues to be used in association with the GMO

PART 4: ADDITIONAL INFORMATION FOR A GMO THAT IS A WHOLE PLANT OR IS TO BE USED IN CONJUNCTION WITH A WHOLE PLANT

4.1 Stage of plant development to be grown

4.2 Growing medium for the plants

PART 5: RISK ASSESSMENT AND MANAGEMENT

Health and safety of people, animals and environment

5.1 Biosafety Risk Level

5.2 Pathogenicity risks of the vector or construct

Indicate infectious dose, mode of transmission, host range, availability of preventive measures and availability of effective treatment

5.3 Possibility of aerosol generation

e.g. pollen etc.

5.4 Possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from the proposed genetic modification(s)

5.5 Possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from an unintentional release of the GMO(s) into the environment?

5.6 Related incident and emergency response

5.7 Physical requirements

Indicate the physical infrastructure/facilities required for safe conduct of your dealing

5.8 Operational Requirements

Indicate operational requirement for safe conduct of your dealing

5.9 Transportation of the GMOs outside the contained facility

Indicate if the transformed materials will be transported outside the contained facility, and if so how

5.10 Storage of the GMO

5.11 Personnel suitability and reliability

5.12 Liability and Accountability

Indicate the name and designation of person

5.13 Disposal of the GMOs

5.14 Other actions and precautions to be taken to minimise risks posed by the proposed dealing(s)

Describe other safety measures that will be put in place to minimize any potential risks

PART 6: DESCRIPTION OF THE CONTAINMENT FACILITY

6.1 Information of the facilities to be used

• Give brief description of the containment facility and provide sketch • Facility type: • Physical containment level: • Address:

6.2 Facility contact person details

Name: Business phone number: Mobile phone number: Facsimile number: E-mail address:

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.

7.1 Principal Investigator and Project Supervisor

Principal Investigator of the applying Institution	
Name:	
Signature:	Date:
Project Supervisor	
Name	
Signature	Date:

7.2 Affidavit/Compliance Agreement

Complete the affidavit/compliance agreement *[The affidavit/compliancy agreement is an inseparable part of the application form]*

FORM E: APPLICATION FORM FOR A CONFINED FIELD TRIAL IN TANZANIA

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

☐ **CBI COPY**
☐ **CBI DELETED**
☐ **NO CBI**

General Instructions

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

All sections of this application must be 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.

Submit 5 copies of the application for use by the NBFP in both hard and soft forms by regular mail or courier delivery.

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.

Provide 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 to biosafety regulations of Tanzania

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

Applications must be received by national Biosafety Focal Pont (NBFP) at the address shown below at least **180 days in advance** of any proposed introduction.

Permanent Secretary
Vice President's Office
P.O. Box 5380
Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

The authorizing party shall acknolewdge receipt within two (2) weeks.

PART 1: APPLICANT/ADMINISTRATIVE INFORMATION

1.1 Applicant

Name of Principal Investigator (PI):

Postal address:

Physical Address:

Telephone:

Mobile phone:

Fax:

E-mail:

Attach:
- Current CV
- Name of and Contact of three referees

1.2 Name and address of Institution

Name of institution:

Postal address:

Physical Address:
- Street:
- District:
- Town/City:

Telephone:

Fax:

E-mail:

Website:

1.3 Title and purpose of the proposed experiment

Title:

Purpose:

1.4 Previous Applications or Approvals

Provide 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, supplementary or a renewal

1.5 Proposed Location and Size of Trial:

Provide 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)

1.6 Proposed Duration of Trial:

Expected starting date: Expected termination date:

PART 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.

2.1.1 Plant Species

Common name:…….....… Scientific name:.....……

2.1.2 Centre(s) of Origin

What is the centre of origin of the unmodified plant?

2.1.3 Centre(s) of genetic diversity

What is the centre of genetic diversity of the unmodified plant?

2.1.4 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, availability of free living populations of the plant species in Tanzania

2.1.4 Tendency to:

a) 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.

b) Pest

Is the unmodified plant regarded by agricultural experts as a pest 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.

2.1.5 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

2.1.6 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 effect confinement measures employed in the confined trial.

2.2.1 Describe the Intended Phenotypic Changes (traits) to the Plant

2.2.2 Intended Reproductive Effects

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

2.2.3 What is the source of the gene?

• Is the source of the gene 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.

2.2.4 Changes in Toxicity or Plant Composition

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

2.2.5 Describe

a) The Features of the Genetic Construct Include coding sequences, promoters, enhancers, termination, selection markers and polydenylation signal sequences. Attach a genetic map and describe the method of modification in an annex. *b) The vector(s) used*

2.2.6 Stable Integration of the Inserted DNA

- Indicate the site of Integration of the Introduced DNA
- Indicate how stable integration of the DNA was demonstrated

2.2.7 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 allergenic or toxic to humans or animals

PART 3: IMPACT ASSESSMENTS

- Environmental Risk Assessment (ERA)

  Provide ERA report

PART 4: EXPERIMENTAL DESCRIPTION

Describe 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.

PART 5: GENETIC CONFINEMENT

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

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

5.2 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? If yes, what are the species

5.3 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

5.4 Describe measures in place to control plant volunteers after termination of the experiment

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

PART 6: 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.

6.1 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

6.2 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

6.3 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 crop residues and waste water will be disposed

6.4 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

PART 7: RECORDS, PERSONNEL, AND PLANNING

7.1 Records and Documentation

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

7.2 Contact Details of Site Manager

Name of Site Manager: Postal address: Physical Address: Telephone: Mobile phone: Fax: E-mail: Attach current CV

7.3 Personnel

Briefly describe competence of the PI, Site Manager and key project personnel. Describe 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

7.4 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 8: 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.

7.1 Principal Investigator and Project Supervisor

Principal Investigator of the applying Institution	
Name:	
Signature:	Date:
Project Supervisor	
Name	
Signature	Date:

7.2 Affidavit/Compliance Agreement

Complete the affidavit/compliance agreement *[The affidavit/compliancy agreement is an inseparable part of the application form]*

FORM F: APPLICATION FORM FOR A COMMERCIAL/GENERAL RELEASE OF GMOS IN TANZANIA1

UNITED REPUBLIC OF TANZANIA
VICE PRESIDENT'S OFFICE
DIVISION OF ENVIRONMENT

☐ **CBI COPY**
☐ **CBI DELETED**
☐ **NO CBI**

General Instructions

This application form consists of two main parts which must be completed for **each individual genetically modified plant species** proposed for commercial/general release in Tanzania.

All sections of this application must be 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.

Submit 5 copies of the application for use by the Tanzanian regulatory bodies in both hard and soft forms by regular mail or courier delivery.

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.

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

Conduct a public notification in accordance to biosafety regulations of Tanzania

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

Applications must be received by national Biosafety Focal Pont (NBFP) at the address shown below at least **180 days in advance** of any proposed introduction.

Permanent Secretary
Vice President's Office
P.O. Box 5380
Dar es Salaam
Tanzania
Email: info@vpodoe.go.tz
Fax +255 22 2125297
Tel: +255 22 2113983/2118416

The authorizing party shall acknowledge receipt within two (2) weeks.

[1] This application form is specific for plants released in the environment. Guidelines for release of other GMO applications including animal, microbes and fish will be prepared later by NBFP.

PART 1: APPLICANT/ADMINISTRATIVE INFORMATION

1.1 Contact details of Applicant

Name of Principal Investigator (PI):

Postal address:

Physical Address:

Telephone:

Mobile phone:

Fax:

E-mail:

Attach:

- Current CV
- Name of and Contact of three referees

1.2 Name and address of Institution

Name of institution:

Postal address:

Physical Address:
Street:
District:
Town/City:

Telephone:

Fax:

E-mail:

Website:

1.3 Title and purpose of the proposed project

Title:

Purpose:

1.4 Previous Applications or Approvals

Provide 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, supplementary or a renewal

PART 2: INFORMATION OF THE PLANT

2.1 Brief description of the genetically 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.

2.2 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.
- 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.

2.3 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.

2.4 Brief summary of field trials undertaken

- Submit a list of previously authorized activities with the GMO in
    a) Tanzania
    b) East Africa
    c) 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.

2.5 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.

2.6 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.

2.6 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.

2.7 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.

2.8 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.

2.8 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.

PART 3: IMPACT ASSESSMENT

3.1 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.

3.2 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.

3.3 Pathogenic and ecological impacts

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

PART 4: 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.

PART 5: 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?

PART 6: RISK MANAGEMENT

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

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.

7.1 Principal Investigator and Project Supuervisor

Principal Investigator of the applying Institution
Name:

Signature: Date:

Project Supervisor
Name

Signature Date:

7.2 Affidavit/Compliance Agreement

Complete the affidavit/compliance agreement *[The affidavit/compliancy agreement is an inseparable part of the application form]*