UNITED REPUBLIC OF TANZANIA

Manual for Emergency Measures

Vice President's Office **March 2012**

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ABBREVIATIONS AND ACRONYMS

ABSAC	Agricultural Biosafety Scientific Advisory Committee
BL	Biosafety Level
CFT	Confined Field Trial
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
ER	Emergency Response
GMO	Genetically Modified Organism
MAFC	Ministry of Agriculture Food Security and Cooperatives
MH	Ministry of Health
MIT	Ministry of Industry and Trade
MLF	Ministry of Livestock and Fisheries
NBFP	National Biosafety Focal Point
VPO	Vice President’s Office

DEFINITION OF TERMS

Accidental release - any incident involving an unintended release of GMOs in the course of their contained use which could present an immediate or delayed hazard to the environment and/or human health.

Application: An application is the data package submitted for each GMO intended for use in a contained facility. An application should cover only one transgenic event.

Authorized Party: The addressee of the letter of Authorization. The Authorized Party accepts full responsibility for compliance with the terms and conditions of authorization, including all associated legal and financial obligation

Compliance Infraction: Violation of the terms and conditions of Authorization.

Contained use: Any operation, undertaken within a facility, installation or other physical structure, which involves GMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment**.**

Containment: Act of restricting or preventing the spread, leak or escape of an experimental object**.**

Emergency: An actual or imminent threat to health and safety of human, animals or the environment.

Environment: includes:

(a) ecosystems and their constituent parts; and
(b) natural and physical resources; and
(c) the qualities and characteristics of locations, places and areas.

Genetically Modified Organism (GMO): Any organism which has been altered or produced through genetic engineering, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering. For the purpose of this guideline the terms genetically modified plants, genetic engineered plants and transgenic plants should be used interchangeably.

Human and animal health - This refers to aspects of human and animal health which are linked to the use of a GMO and its intended or unintended release into the environment.

Incident: Any occurrence that causes, or threatens to cause, a breach of confinement of GM plant material

Living organism: Any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

Modern Biotechnology: the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

Permit: A written document issued by the appropriate authority for the introduction of GMOs under conditions that will avoid or minimize associated risks to human and animal health and the environment.

Unauthorized release: Any introduction into the environment of a GMO for which no permit has been granted by the appropriate authority

EXECUTIVE SUMMARY

This Manual for Emergency Measures (MEM) is appended to the Environment Management Regulations 2009. The purpose of this Manual is to provide detailed and structural information on emergency response in case of unauthorized release of Genetically Modified Organisms (GMOs) beyond the permitted areas.

The manual provides the reader with a deeper understanding of the key principles of emergency response targeting various groups of people such as research scientists, regulators, developers of GMOs, consumers, students, policy makers, activists, community based organisations among others.

It explains situations in which an emergency response may be called for as a result of accidental or unauthorized release of a GMO from contained laboratory, confined field trials, during transport, import, export and on transit or from non-compliance with Terms and Conditions provided on safety issues. It also prescribes what to be done in case of a threat.

The manual highlights the need for carrying out assessment of any possible risk or potential harm that may be posed by the GMO(s) and the level of risk posed by such hazards, based on an assessment of the likelihood and consequence of the hazard occurring.

Furthermore, it highlights the reporting process for emergency response and declaration by the Minister responsible for Environment on the threat and how to deal with it so as so to protect the health and safety of human, animals and the environment.

PREFACE

GMOs offer possibilities of addressing important agricultural, industrial, health and environmental problems, but they also present a number of risks that need to be managed. In order to fully realize the opportunities, minimize adverse effects and improve perception associated with GMOs, Tanzania needs to equip itself with essential tools to ensure safety to human, animals and the environment while conducting the GMO activities. One of the important tools is the emergency response in case of unauthorized releases of GMOs to unintended areas.

The Convention on Biological Diversity provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources. It includes the concept of biosafety which refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. This was effected through the Cartagena Protocol on Biosafety which creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The Cartagena Protocol on Biosafety is the first legally binding international agreement governing the movement of Genetically Modified Organisms (GMOs) across national borders. The protocol aims at providing adequate level of safety for the transfer, handling and use of Genetically Modified Organisms (GMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The protocol provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global biotechnology industry. The protocol thus creates an enabling atmosphere for the environmentally sound application of biotechnology, making it possible to derive maximum benefits, while minimizing the possible risks to the environment and human health.

During the conduct of GMO activities, unauthorized release outside the permitted area may occur. The manual addresses the reporting of the incidences and elucidates what need to be done as emergency response to the threats.

These emergency response guidelines will guide Authorized Parties who have already received approval to undertake GMO activities such as contained laboratory research, confined field trial, during transport, import, export and transit of GMOs in the country. The application procedures for undertaking the above mentioned activities are elucidated in the Environment Management Act 2004 and the Environment Management Biosafety Regulations 2009.

This Emergency Measures Manual includes procedures for reporting the incidences and decontaminating the area under the threat through a defined process and authority. The Authorized party is required to refer to the Environment Management Act 2004, the Environment Management regulations 2009, relevant Standard Operating Procedures and this manual to effectively achieve emergency response exercise and escape any hazard that may occur during the application of GMOs in the country.

An Authorized party is required to prepare and submit an Emergency Measures plan after conducting risk assessment. Risk assessment that answer questions on risks to health and safety of human animals and the environment that may occur when performing the proposed activity over and above those posed by the donor or parent organism. The assessment will also indicate possible hazard(s) and the likelihood and consequence of the hazard(s) occurring from the proposed GMO activities.

As far as emergency response in Tanzania is concerned, initial minimum capacity building in risk assessment and development of Emergency Measures plan need to be accorded highest priority and treated as issues which are required urgently to ensure orderly introduction and application of GMOs in the country.

Sazi B. Salula
Permanent Secretary
Vice President's Office

ACKNOWLEDGEMENT

The successful preparation of this Manual for Emergency Measures as a guide to safe conduct of GMO activities is a result of commitment and hard work by many institutions and individuals who deserve a vote of appreciation. Due to space limitation we cannot refer to all of them, but we assure them of our heartfelt appreciation and we value their cooperation and support.

We would like to express our gratitude to the highly committed expert Dr. Roshan Abdallah from the Tropical Pesticides Research Institute (TPRI) who was involved in drafting this Manual. We thank her for her dedication, commitment and expertise in making this a reality.

We are also thankful to a team of experts who critically reviewed this manual and provided useful comments and additions. We would like to recognize in particular the Director of Environment Dr. C. Ningu, Assistant Director of Environment Mr. S. Nkondokaya (VPO), Mr. O. Kamukuru (VPO), Mr. F. Ngerageza (VPO), Mr. T. Bwana (VPO), and Prof Diran Makinde Director Africa Biosafety Network of Expert (ABNE) AU/NEPAD, and Dr. Hector Quemada, Director of the Biosafety Resource Network at the Donald Danforth Plant Science Center, USA.

We are also very grateful to UNEP for providing both technical and financial support in the preparation and publication of this Manual.

1.0 INTRODUCTION TO EMERGENCY MEASURES

Emergency response is an act, which is taken in case of unauthorized release of Genetically Modified Organism (GMO) to areas where it was not intended to be. An unauthorized release might occur when GMO activities is carried out during transit, transport, import, export, contained use or confined use of GMOs and their products.

It is recognizing that unauthorized release of GMOs into the environment may have significant adverse effects on the environment, and may also pose risks to human and anmals health.

Hence, the aim of this manual for Emergency Measures (ER) is to protect health and safety of human, animals and environment by identifying possible ways accidental release may happen during the application of GMOs. This manual should be read in conjunction with Environment Management Act 2004 and the Environment Management Biosafety Regulations 2009. As per the Environment Management Biosafety Regulations 2009, the National Biosafety Focal Point (NBFP) shall ensure that, where necessary, before any release is made:

a) An emergency plan is drawn up for the protection of human and animal health, biological diversity and the environment in the event of an accident and the appropriate emergency and other services are informed of this plan in writing; and

b) The Authorized Party shall develop an emergency measures plan and submit to the National Biosafety Focal Point before any application of GMOs is conducted in the contained, confined areas, transport, import, export and transit. The emergency measures plan shall include:
    i) Methods and procedures for controlling the GMO(s) or products thereof in case of unexpected spread

ii) Methods for decontamination of the areas affected, e.g. eradication of the GMO(s) or products thereof

iii) Methods for disposal or sanitation of plants, animals, soils, etc, that were exposed during or after the spread

iv) Methods for the isolation of the area affected by the spread

v) Plans for protecting human health and the environment in case of the occurrence of an undesirable effect

c) The Authorized Party shall inform the National Biosafety Focal Point (NBFP) of any accident immediately and provide the following information:

i) the circumstances of the accident;

ii) the identity and quantity of the GMOs or products thereof released;

iii) any measures necessary to assess the effects of the accident on the environment, biological diversity and human and animal health as well as taking into account socio-economic, cultural and ethical concern; and

iv) the emergency measures that has already been initiated by the Authorized Party.

d) Information on safety measures and procedures to adopt in the case of an accident is supplied to persons liable to be affected by the accident. The information shall be updated and supplied periodically. It shall also be made available to the general public.

2.0 OBJECTIVE OF THE MANUAL

The objective of this Manual for Emergency Measures is to provide guidelines to allow effective and timely response in an emergency situation while ensuring the health and safety of human, animals and the environment.

3.0 SCOPE

This manual provides general instructions and guidelines for all aspects of emergency measures while the GMO activity is in the contained, confined, transport, import, export and transit or before release for commercialization in Tanzania. The guidelines provide detailed instructions for emergency measures in case of unauthorized release of GMOs.

The procedures provided here are for the use of all Trial Managers, Technical personnel, agents of the Authorized Party, and government officials engaged in planning, conducting or overseeing GMO activities in Tanzania. This manual is intended as guidance and should not be considered as the only authoritative source. Readers are encouraged to seek additional guidance from the NBFP and other regulatory bodies.

4.0 SITUATIONS FOR EMERGENCY MEASURES

Situations in which an emergency measures may be called for in the case of an unauthorized release of a GMO into the environment.

5.0 REPORTING THE INCIDENTS

All unauthorized release involving GMOs must be reported to the NBFP immediately.

All personnel working with GMOs should be familiar with the protocols in place for their area with regard to GMO activities and reporting incidents for emergency measures. Thus, in the event of an incident or emergency involving GMOs:

i) alert the Facility Manager
ii) alert other relevant personnel - principal investigator, your supervisor, Head of organization, Security, Emergency Services, etc
iii) consult the area safety manuals, standard operating procedures or 'emergency plan' and where appropriate, take emergency action(s) to contain the unauthorized release.

iv) report the incident to your local Biosafety Inspector

v) submit appropriate accident or incident reports as may be required

vi) report the incident to the IBC and notify any other authorities as may be required by this manual

5.1 Corrective Action in Case of an Unauthorized Release involving GMOs

In case of any unauthorized release involving GMOs, all attempts shall be made to recover as much of the regulated GMO as possible and destroyed.
The location of the release shall be marked and monitored and shall be treated in a manner that ensures that no additional release of material occurs. The period for monitoring shall be determined by NBFP.

The unauthorized release shall be immediately documented by the Authorized Party in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Authorized Party and copies shall be submitted to the Chief Regulator of the relevant discipline.
In case of any unauthorized release the Authorized Party shall immediately notify the Chief Regulator orally within 24 hours of becoming aware of the release. The Authorized Party shall also notify the Chief Regulator in writing within 5 working days of the unauthorized release.

All personnel that deal with GMOs shall be familiar with specific safety manuals, standard operating procedures and protocols for emergency measures. These reference documents should be reviewed regularly and updated as required, particularly when new/different GMOs are introduced to an area. Facility Managers shall ensure that all personnel are aware of and have access to the relevant documentation.

The Authorized Party shall ensure that emergency contact numbers (eg. Facility Manager, Principal Investigators) are easily identifiable to all personnel entering a facility and that appropriate 'after hours' emergency contact details are also included.

5.2 Coping with major spills in biosafety levels III-IV facilities

In the event of a spill, the following procedures should be observed:

a) **Avoid** breathing in **aerosol** and vacate the area;

b) **Warn** other human and animals to **keep away** from the area (verbally and with signs);

c) **Keep the area cleared** for a minimum of 30 minutes to allow time for aerosols to settle or be diluted by air handling systems;

d) **Remove** contaminated clothing;

e) **Wash** exposed skin;

f) **Notify** laboratory supervisor/ facility manager;

g) If there is a significant risk of infection, consider assembling a clean-up team consisting of three human and animals: one observer and two operators;

h) Use **personal protective equipment** for infection control (gown, gloves, goggles, respirator);

i) After **waiting** at least **half an hour** and wearing protective clothing: assess the extent of the contaminated area;

j) Lay paper towels impregnated with **disinfectant** (hypochlorite) over the spill. **Wait** at least 10 minutes;

k) ***Do not pour disinfectant directly onto a spill as this can produce more aerosols;***

l) **Wipe** over the contaminated area with disinfectant;

m) Transfer contaminated objects to **suitable containers for disposal**;

n) ***Do not steam sterilise material wetted with hypochlorite as toxic chlorine vapour will be produced*****;**

o) **Decontaminate** or steam sterilise protective clothing or equipment;

p) Complete an '**incident report**';

q) **Notify** your supervisor and the Institutional Biosafety Committee.

6.0 REQUEST FOR EMERGENCY MEASURES

The Minister responsible for Environment may receive request for emergence response from the most relevant of the Chief Regulatory Officer in the area of food safety, animal health, agriculture, environment or any person prescribed by the Environment Management Biosafety Regulations 2009 that:

a) there is an actual or imminent threat to the health and safety of human, animals or the environment;
b) the request shall include proposal on how to adequately address the threat as per the relevant Standard Operating Procedures (SOPs).

In preparing the proposal, the relevant Chief Regulatory Officer should clearly articulate the nature of the actual or imminent threat to the health and safety of human, animals or the environment and how to adequately address the threat. The proposal shall include:

a) the circumstances which have led to the existence of the emergency and/or its identification;
b) the nature and seriousness of the threat, including as relevant, potential proportion of people, animals, plants or type or component of the environment that might be harmed, and potential degree of harm;
c) whether the threat has been anticipated in national emergency preparedness arrangements or strategies;
d) the range of options (operational measures) for addressing threats identified in those arrangements or strategies;
e) if the threat has not been anticipated in national emergency preparedness arrangements or strategies, the status of national emergency measures planning in progress at the time the relevant Chief Regulatory Officer provides the request.

The Minister must also receive advice from the relevant Chief Regulatory Officer of any risks that may be posed by the proposed emergence response and how they can be

managed in such a way as to protect the health and safety of human, animals and the environment. The Minister may request advice from other relevant authorities once the report from the Chief Regulatory Officer has been received.

The Chief Regulatory Officer will forward the risk management plan to enable manage the risks to protect the health and safety of human, animals and the environment. The Chief Regulator will also consult with other relevant regulatory Officer and personnel or other experts as appropriate in preparing the risk management plan.

7.0 EMERGENCY MEASURES PLAN

In order to prepare the Emergency Measures plan, an assessment of any possible risk or potential harm that may be posed by the GMO(s) and the level of risk posed by such hazards, based on an assessment of the likelihood and consequence of the hazard occurring must be carried out:

The risks that is required to be assessed are:

a) Risk to the health and safety of humans from the activities associated with genetic modification.
b) Risk to the health and safety of humans from an unintentional release of the GMO(s)
c) Risk to the environment from an unintentional release of the GMO (s)

The Emergency Measures plan indicates risk management actions to ensure that unacceptable risks are not realized. The plan shall be compiled from specific approved protocols and/or standard operating procedures relevant to the GMO activity which include:

a) Plans for protecting human, animals and the environment in case of the occurrence of undesirable effects that may be observed during contained, confined, transport, import, export, transit activities;

b) Methods for removal of the GMO (s) in the affected areas in the case of an accidental release;
c) Methods for disposal of other plants animals and any other organisms exposed during the unintentional release;
d) Methods for isolation of the area affected by the unintentional release;
e) Details of other contingency measure that will be in place to rectify any unintended consequences if an adverse effect become evident during the application of GMO activities or when an unintentional release occur.

8.0 EMERGENCY MEASURES DECLARATION

The Minister responsible for Environment must not declare an Emergency Measures unless he or she is satisfied that GMO poses a threat and that Emergence Response would help respond to the threat.

Before issuing an Emergency Measures, the Minister must be satisfied that the emergency measures will adequately address the threat and that any risks posed by the GMO activities are managed to protect the health and safety of human, animals and the environment.

In preparing the report, the relevant Chief Regulatory Officer shall clearly articulate the nature and seriousness of the threat posed by the GMO.

8.1 Declaration of Emergency Measures

The NBFP will communicate the Emergence Response to the affected districts and Regions in the following manner:

a) Initial notification will occur as soon as practicable after the Minister responsible for Environment is advised by the relevant Chief Regulatory Officer that there is a threat and that making an Emergency Measures would

help address that threat. This notification should include the relevant Chief Regulatory Officer's original advice;

b) Following the initial notification, the Minister responsible for Environment will undertake formal consultation in writing to the relevant Districts and Regions providing:
    i) the relevant Chief Regulatory Officer's original advice and any further clarifying or amending information;
    ii) a draft of the Chief Regulator's initial risk assessment advice;
    iii) details of associated approvals issued or being considered by other national regulatory
    iv) authorities if any;
    v) description of the broader emergency measures coordination.

c) Districts and Regions will be given 48 hours to comment on the making of the proposed Emergency Measures – failure to respond within this time will be taken as tacit consent.

d) After the 48-hour comment period, the Minister responsible for Environment will consider the advice and any District and Region's comments and consult the Chief Regulator regarding any comments on the risk assessment before declaring an Emergency Measures. The Districts and Regions will then be notified, including the Emergency Measures made after the Chief Regulator's final risk assessment advice.

8.2 Registration of an Emergency Measures

If Emergency Measures is made it will be registered publicly as a legislative instrument. In addition, the NBFP will update the Record of GMO and GM Product activities to provide details of the Emergency Measures or a license issued subsequent to the making of, and in relation to, an Emergency Measures. The NBFP will also provide details of any breaches of conditions as part of regular quarterly reporting to the Minister

Responsible for Environment. The NBFP will also notify the relevant jurisdiction where the breach occurred.

8.3 Facilitation of Emergency Measures

The Chief Regulatory Officers through their Competent Authorities shall provide advice to the NBFP. The Competent Authorities in the various relevant ministries include:

a) The Agricultural Biosafety Scientific Advisory Committee (PS- MSFC);
b) Food Safety, Ministry of Health
c) Animal Health, Ministry of Livestock and Fisheries
d) NEMC-VPO;
e) TBS-MIT.

9.0 PERIOD OF EMERGENCY MEASURES

An Emergency Measures is valid for a maximum period of six months. The Minister responsible for Environment may extend the Emergency Measures for up to six months only if certain preconditions are met. To extend an Emergency Measures the Minister responsible for Environment must:

a) have received advice from the relevant Chief Regulatory Officer who originally provided advice on the need for the Emergency Measures that the emergency still exists and that extending the Emergency Measures would, or would be likely to, adequately address the threat;
b) have received advice from the Chief Regulator that any risks posed by the extension are able to be managed;
c) be satisfied that the threat still exists, that the Emergency Measures would adequately deal with the threat and that any risks can be managed in a way which will protect the health and safety of human and animals and the environment.

The Minister responsible for Environment may extend the Emergency Measures more than once providing that the same preconditions described above are satisfied. Despite

provision to extend an Emergency Measures more than once, the intention is that ongoing use of the GMO beyond emergency circumstances requires authorization through normal assessment and licensing processes.

The relevant Chief Regulatory Officer will be advised by the Minister responsible for Environment that the Emergency Measures will not necessarily be extended and recommend that they contact the potential Authorized Party to advise for continued activities of GMO hence, she/he should re-apply for a permit as per the Environment Management Regulations 2009 and the EMA 2004.

10.0 VARIATION OF EMERGENCY MEASURES

The NBFP shall review the permit for Emergency Measures within six months and as a result of the review outcome, can make relevant changes accordingly.

The Minister responsible for Environment may vary the conditions of an Emergency Measures if a variation is administrative in nature. If the variation is substantive then the stakeholders must be consulted to get their inputs.

The Minister responsible for Environment may amend an Emergency Measures permit on a certain GMO Regulation after:

a) receiving advice that the GMO no longer poses an actual or imminent threat to the health and safety of human and animals and the environment;
b) receiving advice that the declaration of the GMO is no longer required to respond to a threat;
c) consulting with stakeholders.

11.0 SUSPENSION OR REVOCATION OF EMERGENCY MEASURES

An Emergency Measures will come to an end six months from when the Emergency Measures took effect, or on an earlier date specified in the permit. The Minister

responsible for Environment may suspend or revoke an Emergency Measures before it is due to come to an end if she/he:

a) becomes aware of risks posed by the GMO that cannot be managed safely;
b) is satisfied that the emergency no longer exists or is no longer sufficiently actual or imminent to justify an Emergency Measures; or
c) is no longer satisfied that the GMO adequately poses the threat.

12.0 REVIEW OF THESE GUIDELINES

These Guidelines were developed in March 2012 and reviewed by stakeholders. They will continue to be reviewed as need arises, as identified by the NBFP.

The Environmental Management Act (2004), administered by the Ministry responsible for Environment, provides authority to regulate the importation, development, handling and use of GMOS and their products.

13.0 REPORTS AND FORMS

Adequate records are critical to establish the compliance of the Authorized Party with the Terms and conditions of authorization and other relevant requirements. Clear, authentic and readily accessible records shall be maintained to document critical activities. NBFP therefore publishes the attached example forms, which may be used by the Authorized Party for guidance in developing forms for use in their specific emergency measures.

All Authorized Parties shall report the progress of the emergence measures activities accordingly. The following summary reports are required for each GMO activity.

a) Interim Report

The Authorized Party shall submit an Interim Report within one week after the termination of the emergency measures exercise summarizing the incidence, methods used for emergency measures and any unanticipated effects.

b) Final Report

The Authorized Party shall submit a final report within two weeks after the completion of the emergency measures activities. Any non-compliance shall also be reported and any measures taken to bring the trial back to compliance.

c) Report Forms

The forms provided are intended as example formats for collecting typical information required for documentation of compliance requirements. These forms may be customized in the Terms and Conditions of authorization for a particular incident. Similarly, the formats suggested for reporting of results may also be modified if needed to meet specific requirements set forth by the NBFP for a particular incident.

ANNEX 1

EXAMPLES OF RECOMMENDED REPORT FORMS

APPLICATION FORM FOR EMERGENCY MEASURES

REFERENCE NO……

Instructions for Completing Forms

i. Record information directly, promptly and legibly with blue or black pen or electronically. Do not use pencil or whiteout. Capitalize written information.

ii. Date format is Day, Month, Year. Use metric (SI) units such as kg. m. ha for information.

iii. If there is not enough space on a page to record all data or explanations needed, add extra pages and complete the entry there.

iv. Areas left blank for any reason must be lined-out, initialed and dated.

v. It is acceptable to carry identical information down through a column by use of a line drawn between the first entry and the same entry repeated in the last space of the column.

vi. Changes to entries should be made by drawing one line through the original entry so as not to obscure it, indicate the reason for the change, then initial and date entry.

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

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 to the National Biosafety Focal Pont (NBFP) at the address shown below:

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

Applicant/administrative Information

Applicant:
[Name of Principal Investigator and applying institution]

Contact Details of Principal Investigator (PI):
Name of PI:

Postal address:

Physical Address:

Telephone:
Mobile phone:
Fax:
E-mail:

Title, purpose and place the GMO activity and the type of threat

Title:

Purpose:
Type of threat:

Previous Applications and Approvals:

Proposed Location and Size of area under threat:
[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 Emergency Measures:

Expected starting date:

Expected termination date:

Contingency Plans included in the application:

Name of Principle Investigator			Department			
Contact No	Day:	Evening/Weekend		E-mail		
Name of personnel Working on project*			Position			
Name of personnel Working on project*			Position			
Name of personnel Working on project*			Position			
Contact No	Day:	Evening/weekend		E-mail		
Are there introduction of pathogens insects, recombinant organisms or hazardous materials intentionally/accidentally introduced?			YES		NO	
Yes (please specify)						
Was the GMO moved out of the permitted area?	NO		YES			
If YES (Please specify and attach a Risk Assessment & Risk management plan)						
How long will Emergency Measures be needed?		Mode of measures				
Specify any specialized equipment needed:						
I have read the Emergency Measures Manual and agreed to comply (tick)			YES		NO	
I have attached a Risk Assessment and Emergency Measures plan to this application (tick)						
Personnel's Name & Signature:			Principle Investigators Signature and Stamp:			
Personnel's Name & Signature :						

Personnel's Name & Signature:					
Date:		**Date:**			

* Attach additional sheet with details if necessary

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.

Authorized Party

Name:

Signature**:** Date:

Project Supervisor (Institution Head)

Name:

Signature Date:

For official use only

Date received	
Name	
Signature	
Remarks	