Government of the People's Republic of Bangladesh

Emergency Response Procedures for GMOs in Bangladesh

Implementation of the National Biosafety Framework of Bangladesh Project
Department of Environment
Ministry of Environment, Forest and Climate Change
June 2018

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Table of Contents

PREFACE

Biotechnology is being used to solve problems which are not possible to solve by conventional technology in the field of agriculture, industry, medical and environment. But it has potential risks that need to be addressed.

In order to fully realize the opportunities, minimize adverse effects and improve perception associated with GMOs, Bangladesh needs to develop all essential tools to ensure safety to human and animal health and the environment while conducting the GMO activities. One of the important tools is the emergency response procedure in case of unintended releases of GMOs into the environment.

The Cartagena Protocol on Biosafety is the first legally binding international agreement providing the guidelines for the safe use, transfer, handling and movement of Genetically Modified Organisms. Bangladesh as the signatory of the protocol is committed to implement biosafety regulation in the country. Bangladesh has already developed and enacted biosafety rules, biosafety guidelines and other regulatory documents.

During the application for permission for GMO research, field trials or introduction, each applicant needs to submit Emergency Response Plan related unintentional or accidental release of GMO outside the permitted area.To address the spread of GMOs in the environment, this ERP has been developed to address the emergency situation.

These emergency response procedures will guide Parties who are working with contained laboratory research, confined field trial, transport, import, export and transit of GMOs in the country. The application procedures for undertaking the above mentioned activities are given in the Biosafety Guidelines of Bangladesh 2008.

This Emergency Response Procedure/guideline includes procedures for reporting the incidence, corrective procedure and management of the whole situation. The party involved with the GMO activities is required to prepare and submit an Emergency Response Plan during submission of application for permission.

The successful preparation of Emergency Response Procedure as a guide to safe use of GMO in the event of unintended release into the environment.

We would like to express our gratitude to Dr. M K A Chowdhury who was involved in drafting this ERP. We are also thankful to other of experts who reviewed this procedure and provided useful comments and additions.

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

1.0 Background

Emergency Response Procedure (ERP) is a process or act, which is takes place in the event of accident or unintentional release of Genetically Modified Organisms (GMOs) to place where it was not intended to be happened. An unauthorized or accidental release might be takes place when GMO activities is carried out during transit, transport, import, export, contained use or confined use of GMOs and their products thereof. It is established facts that unintentional release of GMOs into the environment may have adverse effects on the human and animal health and environment.

The Convention on Biological Diversity (CBD) adopted in 1992 covered issues related to biodiversity and biotechnology. Cartagena Protocol on Biosafety (CPB) adopted in 2000 provided adequate level of protection in the field of safe transfer, handling and use of Genetically modified Organisms (GMOs) resulting from modern biotechnology avoiding adverse impacts on biological diversity and risks to human health. The Convention has three goals: the conservation of biodiversity, the sustainable use of the components of biodiversity, and the fair and equitable sharing of the benefits arising from the use of genetic resources.

Bangladesh as a signatory of Convention on Biological Diversity and Cartagena Protocol on Biosafety, is committed to ensure safe management of biotechnology activities including research, development, introduction and use of GMOs. In order to safe use and management of biotechnology research and development activities, Bangladesh Government has formed different policy and technical committees and adopted biosafety guidelines, rules, transgenic food safety guidelines and other relevant documents. Any activity with GMO is performed following Biosafety rules and guidelines in the country. Unintended release in the environment may be happened during transport, movement and use of GMO. It is therefore that the country should have guidelines on how to deal with accidents that involve GMOs.

The ERP for GMOs has been prepared to provide a framework for how to handle with GMO in the event of accidental release or unintentional use. This manual gives an outline of ERP of GMOs to ensure an adequate level of protection and safe handling during accidental release of GMOs in the environment. This ERP is designed for the purpose of providing comprehensive guidelines on ERP following laws and regulations related to biosafety in Bangladesh. The Biosafety Emergency Response Procedures serve as guidelines for responding to GMO related unintended release in the environment.

The aim of this Emergency Response Procedure is to protect human and animal health and environment by identifying possible ways of accidental release may happen during the application of GMOs.

2.0 Objective

The objective of this Emergency Response Procedure (ERP) is to provide guidelines to allow effective and timely response in an emergency situation in the event of incident that could be harmful to the environment and human and animal health during handling of GMOs.

3.0 Scope

This ERP provides general instructions and guidelines for all aspects of emergency measures while the GMO activity is in the contained trial, confined trial, field trial, storage, transport, import, export, transit and commercial release. The procedure provides detailed instructions for emergency measures in case of unintended release of GMOs in the environment.

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.

4.0 Emergency Response Plan

Organisation involved in Biosafety research and development activity should have Emergency Response Plan before doing any activity related to use and application of GMOs or its product. As per Bangladesh Biosafety Rules 2012 and Bangladesh Biosafety Guidelines 2008, NCB shall ensure relevant stakeholder to submit Emergency Response Plan during application of contained trial, confined trial, field trial, commercial release, import, export, and transit. Emergency Response Plan may include following issues:

4.1 The Applicant/Party shall develop an emergency measures plan and submit to the NCB during application of GMOs for contained trial, confined trial, transport, import, export and transit. The emergency measures plan shall include:

a. Methods and procedures for controlling the GMOs or products thereof in case of unexpected spread;

b. Methods for decontamination of the affected areas, e.g. eradication of the GMOs or products thereof;

c. Methods for disposal of plants, animals, soils, etc, that were exposed during or after the spread;
d. Isolation of the area affected by the spread;
e. Protecting human health and the environment from the spreading GMOs.

4.2 The Party involved with this activity shall inform the NCB of any accident immediately and provide the following information:
a. the conditions of the accident;
b. the identity and quantity of the GMOs or products thereof released;
c. 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
d. the emergency measures that has already been taken by the Party.

5.0 Reporting the Incidents

Any incidents related to GMO activities, must be reported to the NCB/BCC immediately describing the nature and gravity of the accident.

All personnel working with GMOs should be familiar with the emergency response plan, so that anyone can take necessary steps in case of emergency. Thus, in the event of an incident or emergency involving GMOs following actions are performed:

a. inform the Facility Manager;
b. inform other relevant personnel - principal investigator, your supervisor, Head of organization, Security, Emergency Services, etc;
c. consult the safety manuals, standard operating procedures or 'emergency plan';
d. report the incident to the Biosafety Officer;
e. submit appropriate accident or incident reports as may be required; and
f. report the incident to the IBC and notify any other authorities as may be required by this procedures.

6.0 Application of Emergency Response Procedures

These Emergency Response Procedures has been outlined following Bangladesh Biosafety Rules 2012 and Biosafety Guidelines of Bangladesh 2008. Parties involved in GMO activities, should prepare and submit Emergency Response Plan for accidental release of GMOs before performing any GMO related activity. These procedures are applicable but not limited to the following cases involving a GMO:

a) Contained trials;
b) Confined field trials(CFTs);
c) Release into the environment;

d) import, export and transit;
e) Transport, storage and handling;
f) Food, feed and for processing;
g) Marketing; and
h) Unauthorized release into the environment

7.0 Emergency Response Strategy for Trials and Food, Feed and Processing

7.1 Preparedness Plan

The preparedness plan should cover:

a. Staff training/ capacity building**:** The Parties working with GMO should train all staff members on the identification of GMO. Providing Hands-on training on emergency response procedures including the use of relevant equipment during incident.
b. Identification and storage of equipment: Identify all equipment to be used in case of emergency and ensure proper storage so that it is easily accessible.
c. Standard Operating Procedures (SOPs): SOPs should be in place and all staff should be familiar with them.
d. Security: Ensure that there is proper security (fencing, security personnel, restrictions of access and buffer zones depending on crop orenvironment).
e. Storage of seed and/or harvest or quarantined products: The Party should designate a secured and labelled storage.
f. Transportation: Good condition vehicles must be labelled with GMO and the shortest route for transportation should be used.
g. Regular risk assessment: Identify and monitor critical high risk points.
h. Identification of emergency response agencies: Supply the list of Emergency Agencies to all relevant stakeholder.
i. In case of food, feed and processing, emergency plan includes following issues:
    i. Traceability of the marketed GMO product and proper labelling;
    ii. Separation of GMO and non-GMO to avoid contamination;
    iii. Procedure for Handling of waste and by products emanating from GMO processing;
    iv. Separate storage for GMO products.

7.2 Response Plan

In the event of an accident, the Party shall:

a. Immediately assess the site and notify the office of the NCB/BCC;
b. Full and detailed information on the condition of the accident;
c. Any information necessary to assess the effects of the accident on the health of the general public or on the environment;
d. Put restriction on the area where accidental release is happened;

e. Inform the relevant emergency services (if any) of the accident;
f. Restrict movement of public in the area of incident;
g. Activate other relevant provisions of the emergency plan;
h. In case of food, feed and processing, notify all retailers and other outlet as well as consumer of the product. Immediate removal from the market and cleaning the area; and
i. After implementing all the necessary steps, party should submit a detailed report to the Competent Authority.

7.3 Recovery Plan

The recovery plan should include followings:

a. Establishment of the extent of spread and determine the coverage of the contamination;
b. Ensuring containment facilities to restrict any spread of GMOs;
c. Collecting release materials and engaging law enforcement agencies if necessary;
d. Storage of released material in a secured facility while arranging for appropriate disposal;
e. In case of food, feed and processing, withdraw all distributed stock.

7.4 Mitigation Plan

The mitigation plan should cover the followings:

a. Strengthening security in the event the incidence was caused by inefficiency of the security system;
b. Application of appropriate handling/ treatment/ final disposal of released material;
c. Quarantining of any suspected persons or animals until they are certified safe and free from the contaminant of GM material;
d. Compilation and analysis of the incidence report in order to inform the review of the emergency response strategy;
e. Providing compensation of any affected party due to incident; and
f. In case of food, feed and processing, destroy all withdrawn GMO products and compensate all affected stakeholders.

After getting notification on an accident, NCB shall engage an independent committee to investigate and assess the condition and nature of the incident. The committee shall make a full analysis of the accident and provide recommendations to avoid a similar accident in the future. NCB may instruct party involved with the incident provide costs incurred by it.

8.0 Emergency Response Strategy for Unintentional Release into the Environment

Government of Bangladesh has already enacted Biosafety Rules of Bangladesh, 2012 that covers safe application of biotechnology in various uses, including research under containment in the laboratory, field trial, trans-boundary movement, transit, handling and uses of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health. The Provisions-3 of Bangladesh Biosafety Rules 2012 is applicable to all organizations located in Bangladesh involved with biotechnology research. The provisions says that without the approval of Ministry of Environment and Forests, an individual or a firm shall not import, export, buy and sell any Genetically Modified Organism or products, or commercially use them. Thus, unintentional release of GMO into the environment is an illegal activity. In that case unintentional released GMO shall be destroyed immediately. The NCB shall take appropriate action against the Party involved with the unauthorized release of GMO in the environment. The unintentional release of GMO may be occurred in the following situation, but not limited to:

a) GMO materials from Labs/Containment Facilities,
b) GMOs from storage facilities,
c) Fire in GMO facilities,
d) Un-intentional GMOs release during transportation,
e) During Natural disaster,
f) Week physical facility (such as packaging materials, containment facilities, buildings) and security.

8.1 Preparedness Plan

The preparedness plan should cover:

a. Create Awareness among the stakeholders on the potential risk associated with the unintentional release of GMOs;
b. Regular inspection and assessment of GMOs in storerooms, greenhouse, laboratory;
c. Ensure proper security (fencing, security personnel, restrictions of access and buffer zones);
d. During transportation appropriate type of vehicle should be used and labelled;
e. Identify and list all relevant stakeholders to be contacted in case of emergency and their contacts;
f. Communicated the emergency preparedness plan to all relevant stakeholders particularly those who are part of the response plan.

8.2 Response Plan

In the event of any incidents, the Party subject to any requirements of the NCB, shall:

a. Immediate after the incident, the party should inform the office of the NCB and other relevant stakeholders of the nature, condition and location of the damage or accident;
b. Party shall evaluate the gravity of the incident;
c. Put restriction on the movement in the area or sealed the area;
d. Take appropriate preventive measures to stop any adverse effect from occurring

as a result of the activity; and

e. Compile and submit a detailed report to the NCB on the immediate response measures undertaken within 2days.
f. After getting the information about the incident, NCB shall send a team of expert to identify the person/organisation responsible for the incident, evaluate the level of damage and incur damage costs.
g. Communicate the decisions of the NCB for take necessary action.

8.3 Recovery Plan

During the recovery process the operator shall:

a. Establish the extent of spread and determine the coverage of the contamination;
b. Partner with local and other authorities in the process of recovery;
c. Ensure containment to restrict further spread of the GMOs;
d. Ensure safe storage prior to disposal of recovered GMOs.

8.4 Mitigation Plan

a. Clean –up / site remediation;
b. Appropriate handling / treatment / final disposal of released material.

9.0 Other cases

In the event an accident results from a case not covered above, the provisions stated in and 7.0 of these procedures shall be followed.

In all cases covered in this section (section 7.0 of these Procedures) the NCB has the responsibility to monitor the implementation of the procedures by parties through information forwarded to it and site inspection. Annex 1 provides a check list that can be used as one of the tools for this purpose.

10.0 Awareness on the Emergency Response Procedures

The NCB shall endeavour to inform all parties and other relevant stakeholders about these procedures. Stakeholders shall be expected to know relevant sections according to their intended GMO activities and develop their own emergency response plans which they shall forward to the NCB along with application for research, contained trials, environmental release and placement of the product into the market. The stakeholders should ensure that their staff members are trained on Emergency Response Procedures.

Abbreviation and Acronyms

BL	Biosafety Level
CFT	Confined Field Trial
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic Acid
ERP	Emergency Response Procedure
GMOs	Genetically Modified Organisms
MoEF	Ministry of Environment and Forests
NCB	National Committee of Biosafety

Glossary of Terms

1. **Accidental release** - any incident involving an unintended release of GMOs in the course of their action which could present an immediate or delayed hazard to the environment and/or human health.
2. **Authorized Party:** The addressee on the notification of authorization who shall accept full responsibility for compliance with all terms and conditions of authorization.
3. **Biosafety-** the policies and procedures adopted to ensure the environmentally safe application of biotechnology.
4. **Biosafety Legislations-**Biosafety legislations include the Bangladesh Environment Conservation Act, 1995; The Bangladesh Environment Conservation Rules, 1997; the Biosafety Rules of Bangladesh, 2012; and the Biosafety Guidelines of Bangladesh, 2008.
5. **Biosafety Authority-**Biosafety Authority in Bangladesh includes Ministry of Environment, Forest and Climate Change (MoEFCC); Department of Environment (DoE) of MoEFCC; National Committee on Biosafety (NCB); Biosafety Core Committee (BCC), Field-level Biosafety Committee (FBCC); Institutional Biosafety Committee (IBC).
6. **Biotechnology-** any technique that uses living organisms or substances from these organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses.
7. **Biological Safety Officer (BSO) :** Under Biosafety Guidelines there may be designated Biosafety Officers at the institute level who will be responsible for ensuring and implementing the issues of Biosafety at the institute level. According to Cartagena Protocol on Biosafety,the Officer/s under competent national authority who will be responsible for endorsing Biosafety related clearance in favor of the application of the proposals of import for contained use or commercial release of GMOs/LMOs.
8. **Compliance-**Means actions are taken to determine if organisations/individuals are acting in accordance with legislative requirements and/or sanctions applied to encourage accredited organisations/individuals to act in accordance with legislative requirements.
9. **Contained use-** any operation, undertaken within a facility, installation or other physical structure, which involves GMOs/LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.
10. **Containment-** act of restricting or preventing the spread, leak or escape of an experimental object.
11. **Damage** means an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
12. **Enforcement-**Means actions taken when a organisation or person is not complying with legislative requirements and it is necessary to undertake those actions in accordance with the Act in order to protect the health and safety of people and the environment.
13. **Environment-** humans and their surroundings including the earth's sub-surface.
14. **Genetically Modified Organism (GMO)-** a genetically-modified organism. These are living organisms whose genetic material has been altered or modified by any of the varieties of techniques

of modern molecular biology to make them capable of producing news substances or perform new functions.

15. **GMO-Products-** the products involving Genetically Modified organisms (GMOs/LMOs) can be grouped into two (a) where GMOs/LMOs are used in the process of production but the end product is not GMO (the vaccine, growth hormones etc.) (b) where the end product is GMO (the plants with foreign genes with improved characteristics like resistance to insect, pests or virus etc.).

16. **Incident** an event that leads to exposure of human health and /or environment to risks associated with a GMO.
17. **Introduction into the Environment** means any deliberate use of GMOs, subject to this Act, that is not contained use, but does not include GMOs imported for direct use for food or feed or for processing;
18. **Monitoring-**Monitoring means to make observations and to check that legislative requirements for ensuring biosafety are being complied with.

19. **Modern biotechnology-**Means application of

    (a) In vitro nucleic acid techniques, including recombinant nucleic acid and direct injunction 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.
20. **Non-compliance-**Non-compliance means an inconsistency between an event or state of affairs and the requirements imposed by licence accreditation or certification conditions, or any of the requirements of the law or regulations.

21. **Risk analysis-**Risk analysis includes the probability that, in a certain timeframe, an identified hazard could lead to an adverse outcome in a person, group of people, plants, animals and/or the ecology of a specified area that is exposed to a particular GMO. Typically, risk depends on both the level of hazard of the agent and the level of exposure of the receptor (human, animal, plant, etc.). Risk analysis has two dimensions: probability (likelihood) of an event; and consequence (the impact of the event when it happens).

22. **Release into the environment-** the use of a regulated material outside the physical confinement found in a laboratory, a contained greenhouse, a fermented or other contained structure.

23. **Transgenic animals or plants-** animals or plants whose hereditary DNA has been augmented by the addition of DNA from a source other than parental germ plasm, in a laboratory using recombinant DNA techniques.

ANNEX 1

Emergency Inspection Checklist

Name of Party: ……..……..

Name of Reporting Officer: ……...

Designation: …….…….....

Date of Incident:…….....

Type of GMO: …….....

GM Permit Number: ……....

Issue	Yes	No	Comment
1. Does the Party have a valid GMO Permit?			
2. Was the incident reported on time to the concerned Authority?			
3. Was it an accidental release?			
4. Was it an unintended release?			
5. Was there any non-compliance recorded?			
6. Has the public been informed?			
7. Has the incident report been submitted?			

Date of Inspection: **……...**

Name of Inspector: **……**

Signature: **……**