[Final Draft]

Monitoring and Enforcement Manual

for GMO

Department of Environment
Ministry of Environment and Forests (MoEF)
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Monitoring and Enforcement Manual for GMO
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Introduction

Monitoring is the process of assessment of progress achieved during the implementation of any activity in relation to set objectives. It is a regular and systematic assessment and review of progress of an activity. Monitoring induces the better performance of any activity. Regular monitoring ensures accountability, timeliness and quality of an activity. It provides corrective measures of the activity during the implementation. Field monitoring is the direct inspection of field level activities following set regulations. In case of Genetically Modified Organisms/ Living Modified Organism (GMOs/LMOs), field level inspection includes monitoring for compliance with biosafety regulations and guidelines. Monitoring is an essential part of the implementation of biosafety system in Bangladesh in order to manage the introduction of the products derived from modern biotechnology. Monitoring is also useful to reassure public concern over potential adverse impacts on environment and human and animal health. Because of the potential risk of GMOs on the environment and human health, continuous monitoring and enforcement on various uses of GMOs would ensure sustainable development in the modern biotechnology. Monitoring Officer/Inspector inspects the places of various uses/activities of GMOs following biosafety regulations and guidelines.

The Cartagena Protocol defines a living modified organism (LMO) as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. As a signatory to the Cartagena Protocol on Biosafety, Bangladesh has developed biosafety regulatory system to ensure safe management of modern biotechnology products, including full ranges of policies and procedures to ensure safe application of modern biotechnology through the course of their development and use. In accordance with the Biosafety Rules and Guidelines of Bangladesh the regulatory processes are applied to prevent adverse effects of GMOs on the conservation and sustainable use of biological diversity, taking also into account risk to environment and human and animal health.

The Monitoring and Enforcement Manual for GMOs has been prepared to provide a framework for monitoring and enforcement activities in the country. This manual gives an outline of monitoring and enforcement of GMOs to ensure an adequate level of protection in the field of the safe transfer, handling and use of GMOs/LMOs. This Manual is designed for the purpose of providing comprehensive guidelines on monitoring, compliance and enforcement of the laws and regulations related to biosafety in Bangladesh. In particular, this manual will assist monitoring officers, inspectors, investigators and decision makers and their partners in undertaking monitoring, compliance and enforcement activities related to GMOs release into the environment, importation,

development, packaging, contained use, transfer and field testing and other purposes use in Bangladesh.

1. Objective

The objective of this Monitoring and Enforcement Manual is to provide guidance for effective monitoring, compliance and enforcement activities in development, use, transfer, movement, packaging, contained use, field testing, importation and any other use of GMOs in Bangladesh in order to reduce the risk, if any, of GMOs to human and animal health and the environment.

2. Scope

This manual shall apply to monitoring during development, use, release, transboundary movement, transit, handling and storage of all GMOs.

All public, private and international organizations located in Bangladesh dealing with GMOs shall be monitored in accordance with the guidelines contained in this manual. This manual intends to assist the concerned monitoring and compliance authorities in implementing the monitoring and compliance activities to ensure biosafety in dealing with GMOs.

3. Principles of Monitoring and Enforcement

The basic purpose of monitoring and enforcement is the effective implementation of biosafety rules-regulations. Monitoring and inspection ensure the safe development and use of GMOs. Proper compliance with biosafety regulations requires following attention during implementation of a project/programme related to GMOs:

a. To prevent or reduces the risk to biological diversity taking also into account risks to human and animal health and the environment through effective and efficient monitoring and compliance.
b. To establish the best practices in monitoring and compliance oversight of an accredited institution's dealing with genetically modified organisms.
c. To establish a procedure for monitoring and reporting verifying that a program complies with the conditions under which an approval is given, and the person responsible for monitoring activities may be required to comply with a specific monitoring plan. This will depend on the results of the risk assessment analysis on a case-by-case-basis.
d. To designate a number of inspectors taking into account the different contexts of the case concerned. Specific experience and inspecting methods related to the activities of the GMOs

should be clearly defined by biosafety committees of relevant organisations under the umbrella of the National Committee on Biosafety (NCB).

e. To identify the issues of monitoring, nature of data to be collected and enforce supervision system based on the outcome of risk assessments.
f. To set up appropriate methodology for ensuring effective monitoring system prior to the commencement of monitoring programme and use standard monitoring format.
g. To ensure compliance with legislative obligations consistent with the objectives of the relevant laws and regulations.

4. Monitoring and Inspection Procedure/Stages

The Monitoring and Enforcement Manual covers following stages of development and uses of GMOs ensuring safe application. The standard inspection checklists/forms are to be used during the inspection in addition to inspection and verification of records of various activities in line with the SOPs. Consequently, the monitoring officer will be expected to understand the purpose of each inspection prior to the inspection. The monitoring officer must evaluate previous inspection reports and carry a copy if necessary. The monitoring officer may inspect the documentation before or after inspecting the facilities. The monitoring officer will interview the facility manager or trial manager in addition to perusal and inspection of the records.

4.1. Monitoring of facilities

4.1.1. Research Laboratory Facilities

A Research Laboratory intending to work with GMOs is required to register with the NCB. This kind of laboratory should have qualified personnel, appropriate facilities, equipment and materials for conducting research on GMOs. It is also mandatory for each lab to comply with the Biosafety Guidelines of Bangladesh. NCB provides permission to register a lab working with GMOs/LMOs. Before providing such permission, NCB authority will inspect physical facilities and human resource for doing such research as per Biosafety Guidelines of Bangladesh. Physical containment of transgenic plants and animals within laboratories, tissue culture facilities and growth cabinets must be maintained. And proper labelling of transgenic material should be maintained to avoid any mixing. The standard laboratory regulations must be maintained at all times. All materials being moved from a laboratory working with GMOs should be inspected and or cleaned to ensure that no GMOs will be transported from the laboratory. Registered laboratories will be monitored its facility

during conducting research on GMOs or any other time. Monitoring Format-1 will be used for the monitoring of lab facilities.

4.1.2. Containment Facilities

The monitoring of containment facilities include physical structure and the degree of risk involved with the GMO. Containment term is used for physical barriers to prevent spread of any materials outside the structure**.** Construction details and procedures for handling GMOs will vary depending on the types and degrees of biosafety concern associated with the materials used in the experiment. For transgenic containment facilities may have controlled and filtered airflow, systems of disinfecting material, autoclaves for on-site sterilization facility, and strict limits of entering persons. Contained trial facilities of GMOs research is used to prevent spread any genetic materials in to the environment. It includes disposal of the biological material from the containment. Contained Facilities should be created in such a way that prevents unauthorized entry of personal and disposal of materials in side. Considerations also must be given to safe transport of transgenic materials into and out of the facility. Both physical and biological containment facilities are inspected prior to the programme execution or during programme implementation. Monitoring Format-2 will use for containment facilities monitoring.

4.1.3. Confined Trial Facilities

Confined Trial facilities are meant for preventing the pollen or seed-mediated dissemination of new genes and its persistence in the environment. Confinement measures include maintaining reproductive isolation and strong fencing (or other barriers) to keep animals out and prevent unauthorized harvest. Confined facilities should be created in such a way that prevents unauthorized entry of personal and disposal of materials in side. Safe transport of transgenic materials into and out of the facility should be maintained within confined area. Activities carried out within the facilities are generally performed subject to specific biosafety guidelines. Physical facility is inspected before confined field trial whether it meets the biosafety requirement or not. A monitoring format-3 is used for contained trial facilities.

4.2. Monitoring of Trials

5.2.1 Contained Trial

During GMO development from the laboratory to glasshouse, the basic biosafety requirement needs to be followed to limit spread of the engineered plant and its genetic material. The monitoring of contained trials will be carried out following biosafety guidelines and other relevant documents.

Indicators for monitoring have to be developed in a case-by-case basis with reference to the organism that has been modified, the gene involved and category of risk as well as biosafety level of the facility. Harvest materials are disposed within the containment. All equipment must be cleaned and any living GM material devitalized before removal from containment for disposal. Filter airflow system is maintained to disinfect system. The phenotypic and genetic performance is evaluated in the contained trial. The Authorized Parties will establish a contingency plan for actions to be taken in case of emergency, or of unauthorized or accidental release of GM material. The trial manger keeps record of all relevant data. The monitoring officer will inspect the maintenance of protocols for contained trials. A monitoring format-4 is used for contained trial.

Comment [AR1]: The gene is very rarely the subject of any special monitoring provision. However the ORGANISM plays a huge role in the measure employed in containment.

Comment [AR2]: This may be a true fact, but it has nothing to do with monitoring an enforcement

Comment [AR3]: Sterilization is a very high level of protection. This implies that any and all life forms are killed. If you are trying to maintain containment of a GE plant, this would not be necessary. Plants should be

Comment [AR4]: Every contained facility in Bangladesh working with GMOs will require filter airflow systems? This is not going to work for the net and screen houses which I know are currently in use for GMO containment.

5.2.2 Confined Field Trial

The major issues of Confined field trial with GM crop are maintaining security and control over the material in the field site, maintaining reproductive isolation and preventing the release of plant material from the trial site. In proximity to the trial site area, there should not be field of sexually compatible plant species. For the effective establishment of trial, Authorized Parties are required to follow Standard Operating Procedure (SOPs) describing safe transport and storage, reproductive isolation, material confinement on the field trial site, disposal of GM plant material and removal of volunteers at the trial site. Reproduction isolation must be maintained to avoid gene escape from GM plant to the sexually compatible plant species. Spatial isolation distances vary depending on the reproductive biology of the plant species. Following these, novel genes and their products may be confined to the field trial site and their release into the environment prevented. No plant material from the confined trial site is used as human food /or animal feed. Harvested plant material is disposed as per directions given in the guidelines. The trial manger keeps record of all relevant data. The monitoring officer will inspect the maintenance of protocols for contained trials. Monitoring Format-5 will be used during inspection.

5.2.3. Open Field Trial

Open Field Trial is conducted in a limited scale before commercial release. Boarder row is maintained to prevent gene flow from GM plant to native plant. Out-crossing of GM crop to other crop cultivars should be considered and assessed for environmental contamination depending on crop species. Appropriate training is arranged for personnel dealing with GM crop in the field and GM growing about cultivation practices and maintenance of GM crop. The trial manger keeps record of all relevant data. During monitoring, inspector shall conduct an examination of trial site and

documents in accordance with the Open field trial procedure namely, site security and trial establishment; trial records etc. A Monitoring Format-6 will be used for Open Field trial monitoring.

5.2.4. Post Harvest Monitoring

The primary purpose of the post harvest monitoring is to assess practical efficacy of adopted safeguards of the trial site. This includes maintaining security of trial site, preventing release of plant materials from the site into human or animal food or feed. Both pre-release and post release monitoring are essential in order to determine the GM plant is stable and express no unintended effects in the ecology. Progeny arising from the GM plants at the trial site are known as volunteers, must be prevented from establishing and flowering after termination of the trial. A post harvest period will be defined on the nature of the propagative material remaining in the trial site. Plant material harvested from a confined trial shall be disposed immediately. If any adverse effect is detected its significance should be assessed and if found any potential risk significantly affecting environment emergency control measures should be taken. Details of post harvest management shall be done following the respective SOP. Monitoring Officer shall conduct an examination of the trial site and documents following standard guidelines. A Monitoring Format-7 will be followed during post harvest monitoring.

5.3. Post Release Monitoring

5.3.1. Release to the Environment

The post field release monitoring is one of the important aspects of confinement trials. It is important that tracking and surveillance are undertaken to determine the effect of GM plant on non target plant. Tracking is used to monitor the movement and dispersal of the organisms and their genes. Most crop plants do not survive beyond the cultivated fields. But crop plants those have close relatives in proximity to the cultivated plots; however, there has been concern for outcrossing of the engineered genes. Determination of gene flow to landraces and wild relatives and its consequences need to be assessed. Impacts on biodiversity including to human and animal health need to be assessed after release of GM plant. A Monitoring Format-8 will be used during Field Release to the Environment.

5.3.2. Release to the Market as Food or Feed

The post release monitoring will involve GMOs released in to the market. Following placing a GM product in the market, monitoring and reporting are carried out in accordance with the Biosafety Guidelines. Monitoring will be carried out by both applicant and biosafety authority. The main aspects of monitoring of GM products in the market include the determination of any occurrence and

impact of potential adverse effects on the environment and human health. Occurrence may be of transference of the inserted genetic material to other organisms, including non GM members of the same species or other species of organisms, genetic instability, and adverse interactions with other organisms. Monitoring Format-9 will be followed during market monitoring.

Comment [AR5]: Gene flow between cultivated varieties in agriculture is expected. This would not necessarily be an adverse event, and it should be accounted for in the risk assessment.

Gene flow to other species would be very unexpected and probably would not be accounted for in the risk assessment. However, which organisms will be monitored? How do you plan to monitor for horizontal gene flow? This has the potential to be a very costly waste of time.

5.4. Other Areas of Monitoring

5.4.1. Port of Entry to Address of Importation

The Advance Informed Agreement (AIA) for GMOs applies to the first intentional transboundary movement of GMOs for intentional introduction into the environment of the party of import. The AIA procedure describes that before importation of GMOs in the country, the party of import is notified about the proposed import, receives full information about the GMOs and its intended use. The party of export will take all possible measures to ensure safe movement of GMOs from one country to another. In the port of entry, the inspector/monitoring officer will assess all documents of imported GMOs in accordance with the biosafety protocol. Labeling of containers and damages if any may be carefully examined. A Monitoring Format-10 will be used for monitoring importation of GMOs.

5.4.2. Packaging, Storage, Handling and Transportation

Provision of the Cartagena Protocol on Biosafety describes that each party to take necessary measures for safe handling, transport, packaging and identification during transboundary movement. But this attention is also applicable during internal situation. Shipment of GMOs must be accompanied by documents that clearly identify the organism. Shipment documents should include detail information of exporter and importer, description of organisms, specific requirement of handling, storage, transport and use. Safety of storage of GMOs/LMOs needs special attention. The storage facilities may be at the trial site or outside the trial site in a containment facility. GMO materials are stored before planting, after harvest and before shipment. A storage area must be marked as containing GMO material. Storage facility is inspected before placement of any planting materials or seeds. GMOs intended for direct use as food or feed should be clearly labeled. Packaging, storage, handling and transportation of GMOs are monitored at all stages of development and use. The monitoring officer will use checklist for inspection of storage facility, transportation, and handling. Specific facility inspections may be done to check for compliance or when it is necessary. During monitoring inspector will examine all documents including import and export permit as per guideline requirements'. A Monitoring Format-11 will be followed for monitoring.

5.4.3. Accidental Release and Mitigation

Any accidental release of GMOs/LMOs in to the environment should notify the Competent Authority immediately where accident occurs. The person responsible for the activity of GMOs should provide information on the circumstances of the accident, identify and quantity of GMOs, extent of incident to assess the situation and suggested measure. Concerned Authority will take immediate measures to prevent spillage and risk to human health or to environment. In these circumstances, concerned monitoring team or inspectors will investigate the accident to collect all relevant information and suggest recommendations to avoid similar accident. An emergency plan is necessary for working with risk organisms specifying controlling in case of unexpected spread, method of eliminate the effects of an accident and method of disposal of GMO products, plants, animals, soils, etc. A Monitoring Format-12 will be used for assessment.

5.4.4. Labeling, Traceability and Identification

The box/package/ container carrying GMO or its product shall contain the complete information of its identification on them. Clear labeling must be attached on it stating that it bears GMOs or a product has been produced from GMOs. Proper labeling of containers is critical to ensuring that GMO is prevented from entering into the environment in an uncontrolled manner. The condition of the containers must be checked before using it. The Monitoring Officer will examine issues of labeling and identification. Inspection may be done in accordance with biosafety procedure and following the Monitoring Format-13. The Monitoring Officer will ensure that all the necessary measures are followed before placement of GMOs on the market whether labeling and packaging of GMOs or their product comply with the relevant requirement of biosafety guidelines. GMOs/LMOs are intended to introduction into the environment must be clearly stating traits, characteristics and requirements for safe handling, storage, transport and use.

6. Legal and Institutional Framework of Biosafety

Monitoring and enforcement mechanisms related to GMOs are structured within the broader regulatory regime of biosafety in Bangladesh and hence prior to identify specifically the monitoring and enforcement mechanisms related to GMOs/LMOs, this section provides a brief overview on legal and institutional structures.

6.1. Legal Framework

With respect to biosafety related to GMOs/LMOs, Bangladesh has developed a Biosafety Guidelines in 2008, which is endorsed by the Biosafety Rules of Bangladesh, adopted in 2012 under the Bangladesh Environment Conservation Act, 1995. The Biosafety Guidelines, 2008 formed the basis of the regulatory framework of monitoring and enforcement processes in respect to biosafety in Bangladesh. Therefore, the corresponding legislation of biosafety in Bangladesh includes the Bangladesh Environment Conservation Act, 1995; the Biosafety Rules of Bangladesh, 2012 and the Biosafety Guidelines of Bangladesh, 2008.

Comment [SH6]: Put in appropriate Box

6.2. Institutional Framework

Comment [AR7]: What is the purpose of this section? If it is going to be included it should be at the beginning of the document.

Biosafety systems in Bangladesh involve various ministries and the associated departments working with the modern biotechnology. Ministry of Environment and Forests (MOEF) being the competent national authority and national focal point to the Cartagena Protocol on Biosafety is responsible for the enforcement of biosafety regulatory systems and making oversight on GMO/LMO related biosafety activities in Bangladesh. A number of authorities have been established in Bangladesh to ensure implementation of biosafety under the Biosafety Guidelines of Bangladesh. National Committee on Biosafety (NCB) is the highest authority on biosafety is responsible for environmentally safe application of modern biotechnology. NCB is the final authority to approve any application for GMO development, use and introduction in Bangladesh. Monitoring and enforcement of biosafety regulatory system is lying with NCB. Biosafety Core Committee (BCC) is mandated for providing technical support and accelerating the functions of NCB. Moreover, to ensure safe management of Biosafety activities in the laboratories and in the field there are Institutional Biosafety Committee (IBC) and Field Level Biosafety Committee (FBC). Functions and responsibility of each individual committee are described in the Biosafety Guidelines of Bangladesh.

Comment [SH8]: Replaced by a flow chart in an appropriate system

6.3. Mandates of Biosafety Rules and Guidelines

Biosafety Guidelines of Bangladesh describes the policy and procedures applied to ensure safe application of modern biotechnology taking into consideration of environment and human health. This guideline applies to laboratory and field trial, trans-boundary movement, transit, handling and use of all GMOs/LMOs that may have adverse effects on the conservation and sustainable use of biological diversity and human health. Development of any GMO or its product or introduction should be done following the Biosafety Guidelines. Biosafety Guidelines is mandatory to comply for all laboratories of the government research institutes, universities, international organizations located in Bangladesh, private companies or non-governmental organizations involved in GMO development

and use. The Biosafety Rules is the legal document to enforce matters relating to GMO/LMO development, application, use, introduction, movement, storage or any other related matters. Provisions of punishment for unauthorized use of GMOs/LMOs and make harm to the environment has been defined in the Biosafety Rules of Bangladesh, 2012.

7. Monitoring, Enforcement and Compliance Mechanism

Monitoring is performed at all stages of GMOs development, use, movement, storage, transport, transboundary movement, import, export and any other needed issues. It is used to gather additional scientific data to assist the assessment of risk and decision making. Monitoring will be performed following existing biosafety related rule-regulations, guidelines, manuals, SOPs, and standard monitoring format. Monitoring, enforcement and compliance mechanism is a part of the risk management procedure for biosafety that may involve taking approval, sampling, testing, analysis and reporting to the respective authority for any action, if necessary. Supervision and inspection is to be carried out by the inspectors appointed by the NCB/MOEF. For effective enforcement provisions also needed punishment for any illegal activity that violates compliance provision

The NCB/MOEF is directly responsible for the execution of the monitoring and enforcement mechanism and mandated for establishment of a well organised sustainable national, regional and institutional network for surveillance of risk regarding safety of GMOs. Responsibilities of different regulatory committees for monitoring and enforcement are described in the Biosafety Guidelines.

8. Responsibility of Monitoring Officers/Inspectors

Monitoring officers will be responsible for implementing the task given by the NCB. NCB will delegate authority to undertake monitoring of research laboratory, contained and confined field trial sites, storage facilities, movement of GMOs for the purpose of ascertaining compliance with the terms and conditions of authorization. During monitoring they will follow biosafety rules, guidelines, SOPs, and manuals. The standard inspection checklists/forms are to be used during the inspection in addition to inspection and verification of records of various activities in line with the SOPs. The Monitoring Officer will monitor as per TOR and submit a report with recommendations.

9. Offences and Penalties

Violation of any of the rules, regulations related to biosafety or conditions attached in the particular permission shall constitute an offence. Any pollution of environment or damage of ecosystem caused

by GMO or GM products, the producer, importer, exporter, dealer, transporter, store keeper, and provider of GMO or GM products, shall be liable, unless they prove that they have not been connected with creating pollution of environment or damaging of ecosystem directly. Offences and liabilities under the Bangladesh Biosafety Rules, 2012 is given in Annex-1.

10. Reporting

Monitoring Report must be submitted after completion of the inspection to facilitate immediate decision-making and remedial action. Reports will contain analysis of the situation, identification of gaps and laps and solutions of the problems including supporting evidences. Reports will be submitted to the NCB as per TOR and copied to the authorized party. Reports shall be reviewed by the NCB. The NCB will provide official decision to the authorized party for necessary action.

Monitoring Form-1. Monitoring/ Inspection of Research Laboratory Facilities

Name of the Lab:	**Organisation:**
Location/address:	**Name of the Head of Lab:**
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Inspection:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Is the laboratory registered by the NCB?		
Is the physical facility appropriate for GMO research?		
Is the lab equipment sufficient for GMO research? Provide a list of major equipment:		
Whether the principles of Good Laboratory Practices maintained/followed?		
Whether the health and safety precautions are applied according to national and/or international regulations are maintained/ followed?		
Is there sufficient space and equipment for personnel to discharge duties relevant to the trial ?		
Are there growth chamber and greenhouse facility for growing GM plant?		
Is the lab area secure from unauthorized access?		
Are the researchers and lab technicians trained to conduct GMO research?		
Have all scientists and technicians been recently trained on the GMO development, GMO detection, identification, etc.? Put comments:		
Is there a storage facility for GM plant materials, seeds, tissue culture etc.?		
Is there sufficient space in the storage facility that GM and non-GM materials can be kept separate?		
Describe growth chamber and greenhouse facility suitable for growing GM plant? Comments:		
How the plant is grown in the greenhouse? On benches-, in pots-, in flats. Describe:		
Are the GM and Non GM plant grow separately?		
Is the greenhouse accessed by authorized personnel only?		
Has the greenhouse a double door entry system?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Comment [AR9]: Trained according to what? This is the right thing to check, but in order to do this you can't simply ask the question, you have to be more specific. The monitoring officer will need to check the records of the institution to ensure that the lab workers are trained. This means providing some guidance as to what they are trained in, and how that record is supposed to be kept.

Comment [AR10]: This only applies if the storage space is used for both GM and non GM plants

Monitoring Form-2. Containment Facility Monitoring

Lab Name	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Is the facility secured from unauthorized access?		
Is the physical structure strong enough to protect outside attack by animals and human being?		
Is the physical structure suitable for conduct trial?		
Is the physical structure suitable for preventing spared of any materials outside the structure?		
Has the greenhouse double door protection?		
Is there filtered airflow system to disinfect materials?		
Is there autoclave for onsite sterilization?		
Is there facility for destruction of GM plants in side?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Form-3. Confined Trial Facility Monitoring

Lab Name	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide descri ption where necessary	Yes	No
Is the field trial site marked and protected?		
Is the fencing in place and secured?		
Is there provision for security guards?		
Is the reproductive isolation distance adequate and enforceable?		
Is the necessary equipment available?		
Is there provision for disposal of material in place?		
Is the site properly labelled?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Form-4. Contained Field Trial and Records Monitoring

Lab Name	**Organisation Name:**
Location:	**Trial Manager:**
Name of the Trial	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Are site fences and security measures sufficient to meet requirements?		
Was all GM material planted?		
Has excess planting material been disposed properly or retained in secure storage?		
Do measures for identification/labelling of trial site and plots meet requirements?		
Is the greenhouse kept locked?		
Is the entrance restricted and recorded?		
Has a Record of planting, including a final map of the trial site prepared according to requirements		
Has plant growth and development been monitored and documented according to requirements?		
Are target effects being monitored and documented according to requirements?		
Have any non-target effects been noted?		
If yes, have they been monitored and documented according to requirements?		
Are the genes stable and expressed in all plants?		
Are provisions for training site personnel adequate?		
Are measures for cleaning equipment and personnel adequate to prevent off-site movement of GM material?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Form-5. Confined Field Trial and Records Monitoring

Lab Name	**Organisation Name:**
Location:	**Trial Manager:**
Name of the Trial:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Are site fences and security measures sufficient to meet requirements?		
Was all GM material planted?		
Has excess planting material been disposed properly or retained in secure storage?		

Has plant growth and development been monitored and documented according to requirements?		
Are target effects being monitored and documented according to requirements?		
Have any non-target effects been noted?		
If yes, have they been monitored and documented according to requirements?		
Were any/all prohibited plants in the Spatial Isolation Distance identified and destroyed before flowering?		
Do any buffers, borders and other site details meet requirements?		
Are measures for cleaning equipment and personnel adequate to prevent the off-site movement of propagative GM plant material?		
Is any GM material to be moved off-site for disposal or retention?		
Are the measures in place for on-site disposal adequate?		
Are provisions for training site personnel adequate?		
Have all reports required by the Authorized Party been submitted according to requirements?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Form-6. Open Field Trial and Records Monitoring

Lab Name	**Organisation Name:**
Location:	**Trial Manager:**
Name of the Trial:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Are site fences and security measures sufficient to meet requirements?		
Was all GM material planted?		
Do measures for identification/labelling of trial site and plots meet requirements?		
Has a Record of planting, including a final map of the trial site prepared according to Requirements?		
Do any buffers, borders and other site details meet requirements?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Form-7. Post-Harvest Monitoring

Lab Name	**Organisation Name:**
Location:	**Trial Manager:**
Name of the Trial:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Has the trial prevented release of GM plant materials from the site into human and animal feed?		
Has the trial site prevented establishing and flowering after termination of trial?		
Are volunteers being destroyed and disposed of according to requirements?		
List measures for destruction and disposal of volunteers.		
Has the plant material disposed immediately after the harvest?		
Has the trial followed post-harvest management in accordance with respective SOP?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Format 8. Post Release Monitoring

Lab Name	**Organisation Name:**
Location:	**Trial Manager:**
Name of the Trial:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Has the post release monitoring done as per requirement?		
Has determined any effect of GM plant to non target plant?		
Has the tracking been done to see the movement and dispersal of the organisms and their genes?		
Is there any outcrossing of GM plant?		
Has the gene flow to landraces and wild relatives been assessed?		
Has undertaken the surveillance		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Format 9: Release to the Market as Food and Feed

Lab Name:	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Event:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Whether a detailed compliance of permission is maintained?		
Has the post release market monitoring done as per requirement?		
Whether GMO products clearly identified and labelled with required information?		
Has the GM food or feed maintained its characteristics?		
Has the impact of adverse effects on environment and human health studied?		
Has transferred inserted gene to other organism, genetic instability and interactions with other organisms?		
If required monitoring officer will collect sample in a sample container for analysis.		
Whether any market supervision is done by the party, if yes, how it is performed?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Format 10: Port of Entry to Address of Transportation

Lab Name	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Event:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Has the Advance Informed Agreement applied by the party of import?		
Has the party of import notified about the proposed import?		
Has the party provided full information about the GMOs/LMOs and its intended use?		
Whether the information given by country of export accurate or not?		
Has the party of import taken all possible measures of safe movement of GM materials/		
Whether the product movement ensure and mentioned requirements for safe handling, storage and use?		
Was the labelling of containers OK?		
Was there any damage of containers?		
Specific instruction for safe storage and handling?		

Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Format 11: Packaging, Storage, Handling and Transportation

Section Name	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Event:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Is the packaging done with recommended materials?		
Does the package/box contain full information about the GM materials?		
Is the package proper labeled?		
Is the number of packaging layers sufficient for the material?		
Is each layer of packaging sufficient to prevent loss?		
Is each layer of packaging labelled as required?		
If the packaging has not been retained, has authorization for disposal been documented?		
Is there special area for storage of GM products?		
Is the storage area restricted to authorized personnel only?		
Is the area sign-posted according to requirements?		
Are GM plant materials kept separate from non-GM materials?		
Are GM plant materials clearly identified?		
Has proper care taken during handling and transport?		
Does the container strong enough to prevent any damage during transportation?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Comment [AR11]: What are the recommended materials?

Monitoring Format 12: Accidental Release and Mitigation

Section Name	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Event:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	Yes	No
Any incidents noted?		
If any incidents or compliance infractions have occurred, have they been reported to NCB according to requirements?		
Have corrective actions been taken according to requirements?		

Others (describe)		
Monitoring Officer Signature:	Date:	

Monitoring Format 13: Labeling, Traceability and Identification

Section Name	**Organisation Name:**
Location:	**Facility Manager:**
Name of the Event:	
Name of the Monitoring Officer (s)/Inspector (s):	**Date of Monitoring:**

Put Yes or No against each issues or provide description where necessary	yes	No
Is each container labelled as required?		
Is the container/package containing complete information?		
Has the container checked at the port of entry or after transportation?		
Is the product complying with relevant requirement of Biosafety?		
Others (describe)		
Monitoring Officer Signature:	Date:	

Glossary of the Terms

Comment [AR12]: The glossary is filled with terms that are not used in the document. This needs to be scrubbed.

1. **Authorized Party:** The addressee on the notification of authorization who shall accept full responsibility for compliance with all terms and conditions of authorization.
2. **Biosafety-** the policies and procedures adopted to ensure the environmentally safe application of biotechnology.
3. **Biosafety Legislations-**Biosafety legislations include the Bangladesh Environment Conservation Act, 1995; The Bangladesh Environment Conservation Rules, 1997; the Bioafety Rules of Bangladesh, 2012; and the Biosafety Guiodelines of Bangladesh, 2008.
4. **Biosafety Authority-**Biosafety Authority in Bangladesh includes Ministry of Environment and Forests (MoEF); Department of Environment (DoE) of MoEF; National Committee on Biosafety (NCB); Biosafety Core Committee (BCC), Field-level Biosafety Committee (FBC); Institutional Biosafety Committee (IBC).
5. **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.
6. **Biological Safety Officer (BSO) :** Under Biosafety Guidelines there may be designated Biosafety Officer 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.
7. **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.
8. **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.
9. **Containment-** act of restricting or preventing the spread, leak or escape of an experimental object.
10. **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.
11. **Environment-** humans and their surroundings including the earth's sub-surface.
12. **Field trial:** The planting of one or more GE plants in a single experiment.
13. **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.

14. **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.).

15. **Investigation-**Investigation means an inquiry into a suspected breach of the laws and regulations and corresponding laws and regulations with the aim of gathering evidence. Such investigations are not restricted to purely criminal aspects – in the wider context they may include advice on detected flaws and vulnerabilities in polices, practices and procedures.

16. **Monitoring-**Monitoring means to make observations and to check that legislative requirements for ensuring biosafety are being complied with.

17. **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.

18. **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.

19. **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).

20. **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.

21. **Reproductive Isolation:** Means used to prevent movement or dissemination of genetic plant material by pollen-flow or seed dispersal from the confined field trial site.

22. **Transboundary movement-** the movement of a genetically modified organism to or from Bangladesh/ one country to another country.

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.

24. **Volunteers:** Plants of the same species as the genetically engineered plant material that germinate and grow in the trial site after termination of the trial.

Annex-I. Offences, Liabilities and Penalties in the Biosafety Rules of Bangladesh, 2012 and Biosafety Guidelines of Bangladesh, 2008.

Rule 3. Restrictions on imports or exports on Genetically Modified Organism or products	
Liability	(1) Without any approval from the 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: Provided that provisions of the Guidelines shall be applicable in case of carrying out any research or undertaking and implementing a project on Genetically Modified Organism or products: Provided that approval has to be taken from the concerned ministries, including the Ministry of Agriculture and the Department, if any, in order to market the outcome stemming from the research.
Penalty	Section 10: If an individual or a firm violates the Rule 3, shall be punishable with imprisonment for a term up to two years or with financial fine Tk 10 (Ten) thousand or both.

Rule 5- Identifying or labelling	
Liability	The box or package carrying the Genetically Modified Organism or products shall bear the complete information of its identification on them or bear labelling that states that the product is Genetically Modified Organism or that has been produced from Genetically Modified Organism, and it shall be done additionally, whatever stated in other Acts on the matter.
Penalty	The box or package carrying the Genetically Modified Organism or products shall bear the complete information of its identification on them or bear labeling that states that the product is Genetically Modified Organism or that has been produced from Genetically Modified Organism, and it shall be done additionally, whatever stated in other Acts on the matter.

Rule 7: Reporting of accident, negligence to responsibility, administrative fine, etc.	
Liability	(1)If Genetically Modified Organism or products produced from the organism pose threat to environment, biodiversity and human health or create dangerous situation or pollute environment or cause any accident, the concerned individual or firm shall take necessary initiatives to control the situation, and inform the Biosafety Core Committee (BCC) and the National Committee on Biosafety (NCB) as soon as possible through detailed report or information about the steps taken. (2) If any dangerous situation or accident stated in the Sub-section (1) is created due to negligence of the concerned individual or firm to their responsibility, the individual or the firm shall be held responsible for the situation.
Penalty	(3) The National Committee on Biosafety (NCB) shall take any legal step including ordering a logical administrative fine against the responsible individual or firm under the

	Sub-section (2) after serving an appropriate show cause notice. (4) If the National Committee on Biosafety (NCB) orders any logical administrative fine against the responsible individual or the firm under the Sub-section (3), the financial fine shall be deposited with the concerned Government office within 30 (Thirty) days of the issuance date of the order.

Rule 9.Offence for causing environment pollution or harming the ecosystem	
Liability	If Genetically Modified Organism or products cause environment pollution or harm the ecosystem management, the firms producing the organism or products, their exporters, importers, hoarders, suppliers and retailers shall be responsible for the crimes for the pollution or causing harm to the ecosystem unless they prove that they have not been directly associated with causing pollution.
Penalty	Rule 10: (1)If an individual or a firm violates the Rule 5, shall be punishable with imprisonment for a term up to two years or with financial fine Tk 10 (Ten) thousand or both. (2) If a company is found responsible as a polluter as stated in the Rule 9, the provision under the Section 16 of the Environment Conservation Act will be applicable for that company

Offences and liabilities under the Biosafety Guidelines of Bangladesh 2008 are given below:

3.3 Sanctions against violation of Biosafety Guidelines	
1	In addition to the revocation of the project approval, any violation of the provisions of this guideline or the concealment or withholding by the proponent of any information necessary to evaluate risks to human health or the environment shall be penalized by the concerned ministry by stopping the work immediately and forfeiting the government grants/funds.
2	Further, any incentives that may have been granted the proponent or institution for contributing to advanced scientific or technological research and development will be withheld.
3	These penalties are exclusive of any other penalties tenable by existing law.

Provisions for Appeal and Review

Any person aggrieved with the decision under the Rules 2012 or Guideline can file an application for appeal and review. Provision of appeal and review under the Biosafety Rules of Bangladesh, 2012 is given below:

Rule 11: Appeal	An aggrieved person affected by the order of the Rule 7 shall be able to make appeal under the Section 14 of the Act and the Rules 9, 10 and 11 of the

	Environment Conservation Rules, 1997.
Rule 12: Review	(1) Any aggrieved person affected by the order of the Rule 3 may submit application for review within 30 (Thirty) days of the order a. to the Ministry of Environment and Forests for not getting approval, or b. to the concerned authority where applicable
	(2) Within 30 (Thirty) days of the receiving of the application of the appeal under the Subsection (1),the Ministry of Environment and Forests or the concerned authorities shall settle the appeal, and inform the applicant about the order regarding accepting or rejecting of the application.

Annex II: Some Examples of Minimum Isolation Distances

Plant Species	**Minimum Isolation Distance (meters)**
Solanum melongena L. (Eggplant)	300*
Gossypium hirsutum (cotton)	400*
Zea mays (maize)	400*
Cicer arietinum L. (Chickpea)	3-5*
Carica papaya L. (Papaya)	1000**
Solanum tuberosum L. (Potato)	20***

* Based on requirements for breeders' seed production.

** Bagging buds of hermaphrodite plants is an acceptable physical method to achieve reproductive isolation.

*** Potato is usually vegetatively propagated so this figure is based on experimental methods of pollen flow distance instead of requirements for breeders' seed production

Annex III: Some Examples of Post Harvest Land Use Restriction Periods

Plant Species	**Post-Harvest Period**	**Monitoring Interval**
Gossypium hirsutum (cotton)	1 year	Every 4 weeks
Zea mays (maize)	1 year	Every 4 weeks
Solanum tuberosum (Potato)	1 year	Every 4 weeks
Solanum melongena (eggplant)	3 months	Every 4 weeks
Cicer arietinum (Chickpea)	1 year	Every 4 weeks
Carica papaya (Papaya)	1 year	Every 4 weeks

Annex IV: Some Examples of Non-Compliance with Recommended Actions

Type of Non-Compliance	Advice	Comments
Current Year Inspections		
Guard row/Border row breakdown.	Fall back to isolation distance.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Insufficient Isolation Distance.	Increase the distance and install new permanent markers if circumstances allow and if crop has not flowered.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Prohibited species within the trial site.	Treat them as GEP material, destroy before flowering.	
Prohibited species within the isolation distance (cultivated plants volunteers or weeds).	Remove before flowering/anthesis.	
Prohibited plants allowed to flower and complete anthesis.	Advise as appropriate depending on stage of growth of GEP material, may require increased post harvest monitoring or termination of trial.	A breach of reproductive isolation requiring follow-up, especially with regard to post-harvest monitoring.
Insufficient tenting (damage, delayed setting up).	Advice as appropriate depending on stage of growth of GEP material. Tent must be set up or repaired before plants flower or fall back to isolation distance .	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Torn bagging material used to cover flowers	Bags replaced immediately, fall back to isolation distance if plants already flowering.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated.
Border rows not flowering.	Fall back to isolation distance.	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated
Plants flowering, prior to detasseling/deflowering.	Fall back to isolation distance	When reproductive isolation cannot be re-established by isolation distance, then trial should be terminated
Unauthorized trials.	Trial should be terminated.	
Post Harvest Inspection		
Prohibited species	Remove plants and destroy by	

Type of Non-Compliance	Advice	Comments
within restricted area.	appropriate method.	
Prohibited plants allowed to set seeds	Remove plants and destroy by appropriate method. Site subject to increased post-harvest monitoring restrictions.	Post-harvest monitoring period may be extended.
Inspection of Disposal, Storage and Records		
Poor records	Reconcile this with trial performance. The record may indicate poor trial management	Warning letter to authorized party
Storage of GEP material in leaking or non-labeled containers	Recover spilled material, destroy and clean or monitor site for volunteers. Initiate appropriate labeling immediately.	Follow-up inspections may be necessary
Spills at disposal site	Recover spilled material, destroy and clean or monitor site for volunteers. Initiate appropriate labeling immediately.	Follow-up inspections may be necessary