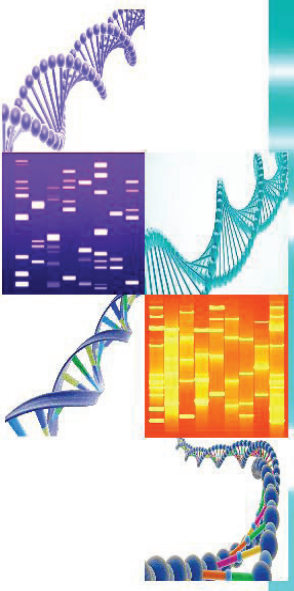

Guidelines for Inspection and Monitoring of GMOs/LMOs

BHUTAN AGRICULTURE AND FOOD REGULATORY AUTHORITY (BAFRA)
MINISTRY OF AGRICULTURE AND FORESTS

FOREWORD

Rapid advancements in modern biotechnology in recent past and adoption in several countries have led to increased global trade of genetically modified organisms/living modified organisms (GMOs/LMOs) and products thereof. This has necessitated the need for putting in place measures for inspection and monitoring of activities involving GMOs/LMOs by countries. Bhutan Agriculture and Food Regulatory Authority (BAFRA), Ministry of Agriculture and Forests is responsible for regulating safety of foods and protection of health and life of plants and animals in Bhutan.

In line with the above, BAFRA has prepared the "Guidelines for Inspection and Monitoring of Activities involving GMOs/LMOs", in transboundary movement with import/export of GMOs/LMOs and their use. These guidelines have been developed keeping in mind the country's biosafety laws/biosafety legislation and at the same time are also in line with Bhutan's obligations as a Party to the Cartagena Protocol on Biosafety, legally binding international treaty in this area.

The document has been developed under the National Biosafety Framework Project of BAFRA, with financial support from the United Nations Environment Program (UNEP) and the Global Environment Facility (GEF). The guidelines will assist the national biosafety office to implement and facilitate monitoring, inspection and enforcement of biosafety decisions involving GMOs/LMOs.

Karma Dorji
Director General

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GUIDELINES FOR INSPECTION AND MONITORING OF ACTIVITIES INVOLVING GENETICALLY MODIFIED ORGANISMS (GMOs)/LIVING MODIFIED ORGANISMS (LMOs)

1. INTRODUCTION

Genetically modified organisms (GMOs) have been developed and commercialized by many countries around the world with applications in agriculture, healthcare, process industry etc. The global area under cultivation of genetically modified crops has been estimated at more than 175 million hectares in 2013. The large scale production of GMOs has resulted in movement of these organisms and products derived from them over national territories for trading. This has prompted the recipient countries to put in place regulatory frameworks for dealing with issues related to transboundary movement of GMOs.

To facilitate the above, the Cartagena Protocol on Biosafety (CPB), an international agreement under the aegis of Convention on Biological Diversity has been agreed by 167 countries as on date. The objective of the CPB is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

Bhutan is a Party to the Cartagena Protocol and Bhutan Agriculture and Food Regulatory Authority (BAFRA) is the designated competent authority to deal with activities involving GMOs/LMOs in the country. Bhutan imports food and feed for use in the country and therefore a need has been felt to have procedures and mechanisms in place for regulating transboundary movement of GMOs/LMOs and derived products. This is in line with Article 25 of the CPB, which requires Parties to adopt appropriate domestic measures to prevent LMOs entry into the country without permission.

The purpose of transboundary movement of LMOs has been classified into three categories as per provisions of CPB:

(i) LMOs for contained use
(ii) LMOs for food, feed and processing (FFP)
(iii) LMOs for intentional introduction into the environment.

However as per the policies of Government of Bhutan, LMOs for contained use and for FFPs may be considered for approvals. However there are restrictions on LMOs for intentional introduction into environment. Accordingly, the scope of the guidelines is restricted to LMOs for contained use and FFPs as indicated below.

2. OBJECTIVE

The objective of this guideline is to provide guidance to designated inspectors

a. to ensure compliance with the conditions set in permissions granted by BAFRA,
b. to ascertain whether the agreed risk management strategies are adhered to by the applicant and
c. to identify any illegal movement/activities involving GMOs/LMOs.

3. SCOPE

These guidelines shall apply to transboundary movement, transit, handling research, field testing and use of all GMOs/LMOS that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health. These guidelines shall apply to inspection and monitoring of activities involving GMOs/LMOs and address the following:

- Point of entry/exit to address import/export
- Contained facilities (Research laboratories, Greenhouses and Storage facilities)
- Field trial sites

- Unintended release
- Non compliance

4. TERMINOLOGY

(1) "Applicant" means a person or agency, national or non-national that notifies its intent and/or applies for an approval to carry out any activity involving GMOs and products derived from GMOs.

(2) "BAFRA" means the Bhutan Agriculture and Food Regulatory Authority.

(3) "Biosafety Clearing House" means the information exchange mechanisms established to facilitate the sharing of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms.

(4) "Contained use" means any operation within a secure 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.

(5) "Emergency" means any significant unintended release into the environment of GMOs or products derived from GMOs, which could present an immediate or delayed hazard to human or animal health or the environment.

(6) "FFP" means for food, feed and processing.

(7) "Genetically modified organisms (GMOs)" means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques. GMOs are also referred to as living modified organisms (LMOs)

(8) "Inspector" means a person authorized by the Ministry of Agriculture and Forests for the purpose of this Act.

(9) "Modern biotechnology" means the intentional manipulation of genes, cells and living tissue in a predictable and controlled manner to generate changes in the genetic make-up of an organism or produce new tissue and includes the application of:

(a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles, or

(b) fusion of cells beyond the taxonomic family, or

(c) mutagenesis that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

(10) "Products derived from GMOs" means products derived directly from them intended for food, feed and processing.

5. DESIGNATED INSPECTORS

Most countries use existing inspectorates, such as plant and quality control officers, to handle biosafety inspections as these officers have authority to carry out inspections and can be additionally trained in the procedures for biosafety inspections. In Bhutan, BAFRA is responsible for the quality and safety of goods and products related to the Ministry of Agriculture and Forests. It also coordinates and liaises with other national, regional and international agencies that are related to regulation of quality and safety of agricultural products including foods. It has two divisions - Quality Control and Quarantine Division (QCQD) and an Analytical and Certification Division (ACD). BAFRA has offices at the entry points, regions, Dzongkhags and major towns of the country including the National Food Testing Laboratory (NFTL) at Yusipang, Thimphu. The major official entry and exit points are Paro International Airport, Gelephu, Phuentsholing, Samdrupjongkhar and Samtse.

As is evident from above, BAFRA has the necessary baseline infrastructure and mandate for implementing enforcement mechanisms with representatives at the entry and exit points. Therefore, Regulatory and Plant Quarantine officers of BAFRA may be designated to carry out inspections regarding GMOs/LMOs. The inspectors shall be suitably trained in the priorities and procedures for biosafety inspections. The day-to-day activities of an inspector would include inspection of imports, shipments, facilities, field trials,

commercial releases, as well as the follow up of reports of non-compliance and the ongoing review of approved GMO activities in the country.

6. PURPOSE OF INSPECTION AND MONITORING

a. The purpose of inspection and monitoring of GMOs/LMOs is to assess and verify compliance with the terms and conditions of authorization.
b. Inspection is needed to determine if contained facilities used for research, storage and production of GMOs comply with regulatory requirements for containment.
c. Inspection of relevant documents ensures that the requirements of data quality and integrity are met.
d. It also provides opportunities to increase awareness of authorized parties and site managers with the regulatory requirements, thus helping to ensure continuing biosafety.
e. The Inspector is available to site managers and authorized parties to answer questions and provide clarification on regulatory requirements.
f. Inspection encourages authorized parties to ensure that regulatory requirements are met. This helps to foster self-regulated compliance and advances the goal of continued and safe utilization and testing of GMOs.

7. CRITICAL POINTS OF INSPECTION AT VARIOUS STAGES

Inspection and monitoring of activities involving GMOs/LMOs may require verification of the documentation and/or site visit to facilities, field trials or storage areas. The critical points of inspection at different stages of operations involving GMOs/LMOs are as follows:

7.1 Point of entry/exit to address imports and exports

The objective of inspection at the point of entry/exit is to ensure that imports and exports of GMOs/LMOs have proper approvals and the shipments are

accompanied with proper documentation. These inspections help in detecting illegal/unintentional imports/exports and taking appropriate measures.

In general the information requirements for import/export of GMOS/LMOS may be provided in different types of documentation such as:

- A commercial invoice;
- A document required or utilized by existing documentation systems; or
- Other documentation as required by BAFRA.

The information requirements vary depending on intended use i.e. contained use, food, feed and processing as indicated below:

(I) Shipments of LMOs for contained use must be accompanied by documentation that:
  - Clearly identifies content as LMOs and as "destined for contained use"
  - Provides the name & address of the consignee, and exporter or importer
  - Specifies any requirements for the safe handling, storage, transport and use
  - Provides further information, where appropriate, such as the commercial name of the LMOs, new or modified traits, transformation events, risk class, use, and any unique identification

(II) Shipment of LMOs intended for direct use as food or feed, or for processing (LMOs-FFP) should be accompanied by documentation that clearly states:
  - Where identity of the LMOs is known, that the shipment "contains" LMOs-FFP
  - Where identity of the LMOs is not known, that the shipment "may contain" one or more LMOs-FFP
  - That the LMOs are not intended for intentional introduction into the environment
  - The common, scientific & commercial names of the LMOs

- The transformation event code
- The website of BCH for information regarding approval status
- The approved use of the living modified organisms
- The suggested methods for the safe handling, storage, transport and use including packaging, labeling, documentation, disposal and contingency procedures, where appropriate

Inspectors have to conduct an examination of documents in accordance with the terms and conditions for transport and shipping, taking also note of the verification if the security and control over the material is being maintained with correct packaging and handling and to confirm that the identity of the GMOs/LMOs is being maintained with clear and detailed labeling.

(III) Sampling: In addition to verification of documents, the inspectors may need to take samples and send to national GMO testing laboratory on a case by case basis. The sampling and testing may be required in cases of any alerts or doubts. It is vital to obtain a representative sample of a size suitable for the required testing The sampling should be carried out as per globally accepted guidelines or protocols such as Codex Guidelines on Sampling (CAC/GL 50-2004), SB/T 10314-1999 (Methods of sampling and rules of test) and ISO 13690:1999 (Cereals, pulses and milled products - Sampling of static batches and "International Rules for Seed Testing by International Seed Testing Association.

Other general responsibilities of the inspectors include

- Regular communication with the BAFRS Competent National Authority regarding LMOs arriving at the ports of entry
- Forwarding LMO import documents to relevant national authorities
- Detecting and alerting relevant authorities about possible illegal imports and unintentional transboundary movements of LMOs

7.2 Facility Inspection

Contained facility inspection includes research laboratories, growth chambers and green houses. It is important that the containment facilities are specified by research laboratories and should conform to the level of hazard that may be caused by the GMO. Both the physical and biological containment facilities needed to be inspected prior to introduction of GMOs. The inspection report format for containment facility is placed at **Annex-1**. In case any pathogenic insurance are being used, medical surveillance of staff may be prescribed as one of condition. A format of medical surveillance report to be applied in such cases is placed at **Annex-2**.

Inspection of the facility and records may be carried out at any time once a facility has been identified for GMO activity, as part of an activity approval. The critical aspects for inspection of the facility are:

- Records for transport of regulated materials,
- Storage areas,
- Containment measures,
- Waste treatment and disposal
- Training of personnel; and
- Availability of guidance documents, such as standard operating systems (SOPs).

Inspectors conduct an inspection of the facility/laboratory and records, taking note of specific requirements in the above areas.

In particular, inspectors will ensure the following with regard to GMOs:

- Facility/laboratory is approved for contained GM activities
- Staff members are trained and training records are available
- Access and containment measures meet national requirements
- Storage areas are secure, separate and labeled.
- Movement of GMOs in and out of storage is controlled and logged
- All waste GMOs are rendered non-viable prior to disposal

- Guidance documents are available for staff members and are up-to-date
- Activity records are available, when required

The facility and documentation inspection under the contained conditions can occur at any time of the year. The quality of data and records for facility inspection should consider the following:

- Inspectors conduct an examination of the activity documentation files and evaluate the adequacy and compliance of the documents with the terms and conditions of the approved activity. Data review helps to ensure that all documentation associated with a regulated GMO activity is available, completed, clear and authentic.
- Data review is useful for confirming compliance with containment and confinement measures, in addition to completion of the required regulatory and technical procedures.
- These records are useful when it is necessary to establish when and how an unintended release may have occurred.
- An exit meeting with the authorized party or site manager is critical to on-going education, understanding and communication about the terms and conditions for activities with GMOs.
- The inspector reviews with the authorized party or the site manager any significant findings from the inspection, and raises any issues, concerns or questions raised by the trial personnel during the inspection.
- In some instances follow up actions and responsibilities may also be discussed and recommendations reported. It may be necessary for the inspector to consult with the regulatory authority to determine how to proceed on some issues.
- In these cases the inspector should inform the authorized party that the regulatory authority will be in contact with them to establish what follow-up action will be required.

7.3 Field trials

Field trials of GMOs are generally done prior to placing on the market/commercial release. Detailed set of guidelines and SOPs need to be in place before permitting field trials of any GMOs. All such trials should be appropriately inspected. As an example, details of a confined field trial sites for GM plants are provided in this section.

In case of GM plants, the field trial inspections are usually planned for the growing season and target specific activities such as planting such as planting, flowering, harvest and post-harvest periods, although not all of these stages may be inspected for each trial. The field trials are restricted in terms of size and number. The format for reporting inspection of a field trial site is placed at **Annex-3**.

The inspectors need to be familiar with the general information about the biology of non GM plant species, genetic modification and potential interactions with the environment. They should be aware of the details of the application to ensure familiarity and have copy of permission/authority letter providing specific terms and conditions. The trial manager is required to provide access to the facility, storage area or trial site and to make all records available for the purpose of inspection.

The inspector is required to ensure the following checks:

- Identity of the material that is planted
- Standard Operating Protocols to prevent accidental mixing
- Verify that the approved isolation distance and/or other containment/confinement conditions are being followed
- To ensure early in the season that there are no other cultivated or free-living plants of the same species and any compatible wild plants located within pollination distance.
- The field site must be clearly identified for the following growing season when volunteer transgenic plants may arise.

- Ensure the machinery/farm tools cleanliness. All tools/equipment is being cleaned prior to and after planting and harvesting the GMO material
- At time of harvest, the procedure for final disposition and revitalization of any harvested material must be carefully inspected These procedures are dependent on the plant, the amount of harvested material, the local conditions and the method selected by the applicant to devitalize any harvested material (i.e. autoclave, steamer, burial, incineration etc.).

The inspectors must submit within a week of each inspection, the inspection report with their observations of the release and the degree of compliance with the biosafety requirements.

7.4 Responding to Non-compliance

It is the primarily responsibility of the applicants to comply with rules and regulations applicable in Bhutan regarding activities involving GMOs/LMOs and take responsibility for any damage or adverse effects that may arise as a result of the use of the GMOs especially with regard to biological diversity and risks to human health.

Inspection and monitoring is undertaken to assist in enforcing compliance with the regulatory requirements. The framework of inspection and monitoring will have a schedule of data and information collection system and in this respect the inspectors will determine frequency of data collection and determine who will collect the data. The inspectors will also ensure that the information collected from the field is passed on to BAFRA headquarters and facilitate fast corrective measures.

However when inspectors discover non-compliance they can respond in several ways. The response is based on:

- national regulatory requirements;
- urgency of the situation;
- level of risk to the environment;
- how readily corrective action can be implemented;
- compliance history of the authorized party

In general, the authorised party may be asked to carry out the corrective action and submit a corrective action report when the issue has been resolved. The regulatory authority will determine whether a second inspection is needed, or they will notify the inspector to confirm the corrective action has been completed on the next inspection of that facility.Generally, if the corrective action will change the terms and conditions of the approval, BAFRA headquarters will need to be informed and to give consent for the action, if it is not already included as an alternative risk management measure for the activity.

In some instances there may not be a clearly identified corrective action, or the proposed corrective action may not be an approved option. In these instances the inspector needs to alert BAFRA headquarters and have them provide an acceptable corrective action and the approval to implement it.

8. QUALITY OF DATA AND RECORDS

Inspectors must conduct an examination of the documentation files in all cases of inspection and evaluate the adequacy and compliance of the documents with the terms and conditions of the specific approved activity. Data review helps to ensure that all documentation associated with a regulated GMO activity is available, completed, clear and authentic. Data review is useful for confirming compliance with containment and confinement measures, in addition to completion of the required regulatory and technical procedures. These records are useful when it is necessary to establish when and how an unintended release may have occurred.

9. ILLEGAL OR UNINTENTIONAL RELEASE OF GMOS

If new information becomes available from different sources about the presence of GMOs/LMOs either illegal or unintentional, it is important to inspect the site and immediately report to BAFRA headquarters.

The critical aspects of effective response to any unintended release of GMOs are:

- Containing the GMOs at the release site
- Timely communication with regulatory authorities
- Removing the GMOs from the site or rendering them non-viable
- Preventing GMOs from being consumed by humans or animals
- Preventing GMO from becoming established and persisting in the environment.

Inspectors also review the corrective action reports related to any unintended release and confirm that the follow up actions were implemented. An inspection of the release site may be required by the regulatory authority, which will provide specific requirements for such inspection, according to the characteristics of the release.

Annex-1

INSPECTION REPORT FORMAT FOR CONTAINMENT FACILITIES

(For use of BAFRA inspecting officer)

Name of inspecting officer: _____

Date of inspection: _____

1. Name of Facility: _____

   Address: _____

   Tel: _____

   Fax: _____

   Email: _____

2. Name of the facility in charge : _____

   Address: _____

   Tel/Mobile: _____

   Fax: _____

   Email: _____

3. Details of contained facility: _____

   Room/Laboratory: _____

   Growth Chamber: _____

   Greenhouse: _____

   Any other: _____

4. Number of scientific/technical staff available in the facility? (please provide details with the educational qualification)

5. Are the Standard Operating Procedures (SOP) in place for research and development, handling, storage and disposal of GMOs/LMOs

   ☐ Yes ☐ No

   (Provide details)

6. Do researchers and laboratory technicians practice and follow SOPs

   ☐ Yes ☐ No

7. How GMOs/LMOs are physically identified in the laboratory?

8. Is the general area secure from unauthorized persons?

9. Are individual laboratories secured?

   ☐ Yes ☐ No

10. Is a sign posted on the facility door stating presence of GMOs
    ☐ Yes ☐ No

11. Are records available for persons entering/exiting the laboratories

    ☐ Yes ☐ No

12. Are records and inventories available for receipt and disposal of GMOs/LMOs?

    ☐ Yes ☐ No

13. Provide details with respect to storage of GM material

14. Is there any risk of GM material such as seeds, tissue cultures, plants material, etc. escaping during the germination process and transfer?

    ☐ Yes ☐ No

15. What kind of “spill response” action plan/equipment is available for items spilled in transit between labs, chambers, greenhouses etc.?

16. What containers are used for carrying items to avoid spillage?

_____ _____

Signature of inspector: Signature of the facility in charge

Annex-2

FORMAT FOR MEDICAL SURVEILLANCE REPORT

1. Personal Details

   i. Name of the Organization: _____

   ii. Name of Personnel: _____

   iii. Designation: _____

   iv. Department:
      a. Phone: _____

      b. Email: _____

      c. Date of Birth: _____

2. Contact with GMOs/LMOs and products thereof:

   Please indicate GMO/LMO products thereof that you work with (tick yes or no):

   i. Do you work with GM technology (rDNA technology)? If Yes please specify

      ☐ Yes ☐ No

   ii. What is the biosafety containment level requirement of organisms handled by you in the laboratory (if applicable)?

      ☐ Yes ☐ No

3. Medical History:

   i. Have you had any change in your health status in the previous year? If Yes,

      ☐ Yes ☐ No

   ii. Have you developed any chronic disease illness in the past year? If Yes, please describe

      ☐ Yes ☐ No

   iii. Have you developed any new allergies in the past year? If Yes, please describe

      ☐ Yes ☐ No

iv. Have you been told by a physician that you have an immunity compromising, medical condition or are you taking medications that impair your immune system (steroids, immunosuppressive drugs or chemotherapy)?

☐ Yes ☐ No

4. If yes to any of the above, please attach a medical surveillance report certified and signed by the registered medical practitioner in the following format:

i. Date of health surveillance

_____

ii. Test or examination performed and results

_____

INSPECTION GUIDELINES FOR FIELD TRIAL SITES

1. Applicants Name: _____
2. Approval number : _____
3. Contact Person (name, Tel/Fax): _____
   _____
4. Plant Species: _____
5. Trait/Gene: _____
6. Location of Site(s) (list each location separately):
7. History of prior use of the plot (last 2 years)
8. Date of inspection: _____
9. Type of inspection (planting, flowering, harvesting, processing, final disposition):
   _____
10. Conditions of the plot according to the approval:
    _____
11. Identity of the field trial (seed storage, planting-harvest site, borders):
    _____
12. Seeds for planting (quantity, conditions):
    _____
13. Conditions of equipment (planting and farming machinery):
    _____
14. Protocols for preparing and managing the field trial plot :
    _____
15. Distance from nearest cultivated area:
    _____
16. Distance from nearest sexually compatible free-living plants:
    _____

17. Description of fields in the vicinity:

_____

18. Presence of volunteer plants from previous field release:

_____

19. Details of confined method being used such as removing flowers, bagging flowers/tassels, physical isolation, temporal isolation etc.

20. Detailed method of disposal of any extra seeds or plants

21. Flowering inspection: describing the pollen management procedures (bagging, de-tassel)

22. Harvest inspection: methods of disposal, cleaning of equipment:

_____

23. Post harvesting (presence of volunteer plants) _____

_____

24. Detailed method of movement and transport of harvested material: out of the plot:

_____

25. Description of final disposal and devitalization (methods)

_____ _____

Signature of Inspector **Signature of applicant**

NATIONAL BIOSAFETY FRAMEWORK PROJECT
BHUTAN AGRICULTURE AND FOOD REGULATORY AUTHORITY
MINISTRY OF AGRICULTURE AND FORESTS
Thimphu, Bhutan
Post Box 1071

PABX – 975-2-327031/325790/325993;
Fax No. 975 – 2 - 327032/335540;
bafraheadoffice@gmail.com
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Website: www.bafra.gov.bt