FEDERAL REPUBLIC OF NIGERIA

Nigeria National Biosafety Inspection Guidelines

August, 2018

Contents

1. INTRODUCTION

These guidelines are to provide instruction for the inspection of Genetically Modified Organisms (GMOs)/ Genetic Modification (GM) facilities by the National Biosafety Management Agency (NBMA) to check compliance with regulatory requirements for export/import, contained research, experimental confined trial sites, post-commercial use, and compliance evaluations on all regulated biosafety activities.

The regulatory requirements for each activity are detailed in the terms and conditions of approval that are issued by the NBMA for each activity. These terms and conditions are contained in the decision document, and Inspectors must be familiar with all of these documents and aspects of biosafety compliance for all the activities regulated nationally in order to discharge their duties effectively.

It is the responsibility of the biosafety Inspectors to undertake and check the level of compliance when they inspect or investigate a specific facility or activity.

1.2 Terminologies Used in this Guideline

Applicant: an individual or institution that submits an application for a GMO activity.

Permit Holder: The individual or institution that received regulatory approval for an activity with GMOs and accepts full responsibility for compliance with the terms and conditions of authorization. This includes all associated legal and financial obligations.

Border rows: A planting of the same or a different plant species around GM plants in the trial site, to serve as a means of reproductive isolation, or as a visual or physical barrier. Also called 'guard rows', or 'pollen trap rows', when used for reproductive isolation.

Compliance: Fulfilling the requirement of all of the terms and conditions of authorization/Permit.

Confined Field Trail (CFT): An experimental field of GMOs not approved for general release, in which measures for reproductive isolation and material confinement are enforced in order to restrict the experimental plant material and genes to the trial site and to remove them from the site at the end of the trial.

Confinement: Restriction of an organism and its genetic traits to a specific and defined area of the environment, called 'trial site'.

Construct: a segment of DNA to be transferred into a cell using recombinant DNA technology.

Containment: putting or placing under a four walled facility.

Event: A single instance of modification of a specific plant species using a specific genetic construct.

Facility manager: The individual responsible for supervision of a storage or research facility

General release: The approved, general use of a GMO with no or minimal regulation. Also termed 'unconfined release', and approvals may have some conditions.

Genetic modification: Modification of the genetics of organism by recombinant-DNA techniques. In this document, the terms '**genetically engineered (GE)', 'transgenic'**, '**genetically modified (GM)'**, and '**living modified organism (LMO)**' are equivalent.

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

Material confinement: Measures taken to ensure that GM plant material is not consumed by humans or livestock.

Non-Compliance: Intentional or unintentional violation of the terms and conditions of authorization.

Pollen Flow: The transfer of genes from one plant to another in pollen by successful fertilization.

Prohibited organisms: organisms that are sexually compatible under natural conditions with GMOs being tested under confinement, and are thus prohibited from the established spatial isolation distance of a confined trial.

Planting material: Plant material such as seeds or cuttings capable of establishing and surviving in the natural environment without human intervention.

Regulatory authority: the government body having statutory authority to regulate an activity in this case the NBMA.

Regulated: In this manual, a GMO that has not been approved for general release

Reproduction isolation: Measures taken to prevent gene flow from organisms in a trial site to nearby sexually compatible species. Also known as 'genetic confinement'.

Sexually compatible: Capable of cross-fertilization and forming viable progeny without human intervention.

Site manager: Person designated by a Permit Holder to be responsible for regulatory compliance at either a contained facility or a confined trial site.

Spatial isolation: a method of achieving reproductive isolation by separating organisms in the trial site by a defined distance from prohibited organisms.

Trial protocol: also known as the '**study plan'**, establishes the technical objectives and required methodology of the trial, including those requirements related to confinement.

Periodic isolation: A method of achieving reproductive isolation by preventing timing of sexual reproduction of two organisms from overlapping, usually by separating the planting dates of the plants or the ovulation times of animals.

Trial Manager: The individual(s) at a particular trial site, designated by the party as responsible for management and compliance of a confined trail. Trial managers are to complete and sign documentation, forms and notes applicable to the trial.

Trial site: The area of a trial that is confined by one or more continuous methods of reproductive and/or material isolation.

Trial site identification: Unique identification code for a single trial site, which is issued by the regulatory authorities, and may be linked to the application code for the trial.

Unmanaged organism: An organism living outside of human cultivation or husbandry and surviving without human intervention.

Volunteer: previously cultivated crop plants germinating in the field during subsequent growing seasons.

1.3 Purpose of the Guideline

The main purpose of this Guideline is to provide instructions to Biosafety Inspectors of the NBMA in carrying out their oversight functions of regulated activities with GMOs. Other purposes include to:

i. assess and verify compliance with the terms and conditions of Permit

ii. determine if containment facilities used for modern biotechnology activities comply with regulatory requirements;

iii. ensure that the requirements of data quality and integrity are met;

iv. provide opportunities to increase awareness of authorized parties and site managers;

v. ensure site mangers and authorized parties answer questions and provide clarification on regulatory requirements;

vi. foster self-regulated compliance and advance the goal of continued and safe utilization and testing of GMOs.

Duties of Inspectors include:

i. logical and step-wise approach in preparing for the inspection, conduct of the inspection of the site and documentation;

ii. interview personnel for pertinent information;

iii. obtaining necessary confirmation of key information;

iv. writing the inspection report, recommendations and implementing any corrective action that may be required;

v. Strict adherence to procedures and the regulatory requirements for activities with GMOs;

vi. safeguarding the environment and preventing any regulated material from entering the food or feed chain.

2.0 AUTHORISATION AND TRAINING

Biosafety Inspectors should have the mandate to enter GM facilities and trial sites in line with national biosafety regulations and other enabling laws. These regulations/ laws give Biosafety Inspectors the authority to seize materials, if necessary. However, most inspections are undertaken with prior notice to the Permit Holder and with the full cooperation of the Permit Holder and site manager.

When approval is given for an activity with a GMO, the NBMA identifies key activities that should be inspected and sets priorities for inspections. It also identifies the critical hazard points that need to be inspected each year. The inspection priorities usually reflect the level of risk posed by a specific activity as a whole, or at a specific time during the activity. In addition, authorised parties that have had non-compliance issues during previous activities are frequently inspected in the subsequent months until the risk of non-compliance is deemed to be low.

The NBMA facilitates the training of Biosafety Inspectors and other relevant collaborating Agencies to undertake biosafety inspections. Inspection trainings shall be for legal officers and scientists to undertake biosafety inspections of contained facilities and field trials. These Inspectors need training in biosafety and basic biotechnology to equip them for inspection of GM activities. There shall be regular training for existing and new biosafety Inspectors to keep all officers up to date with the technology and areas that are considered high risk and require inspection.

2.1 Skills Required for Biosafety Inspection

Biosafety Inspectors need four types of skills:

i. Legal

ii. Technical/Biological Sciences

iii. Organizational

iv. Personal

Legal skills usually come through legal training and qualification as officers of law in the country. Technical skills include a good understanding of ecology, general biology, molecular biotechnology and gene transfer, with willingness to read scientific literature critically and a good understanding of what is needed to run a biotechnology laboratory and testing facilities.

Organisational skills are the most critical for effective performance. The Biosafety Inspectors must develop processes and systems that enable them to cope with increasing numbers of approvals. A slow increase in numbers of applications and approvals will give Inspectors an opportunity to understand their role and to streamline and prioritise their time and procedures.

Inspectors require personal qualities that give them credibility to do their job. These qualities include trustworthiness, integrity and good conduct, a willingness to take oaths of duty, a high work ethic, and good interpersonal skills. The regulatory authority should also require a disclosure of possible conflict of interest.

On-the-job training for Biosafety Inspectors will be required to ensure that Inspectors understand processes and procedures. Inspectors are required to have inspection guidelines so that they can proceed without accompaniment.

3. PREPARING FOR AN INSPECTION

Timing of inspections is set by the NBMA to ensure that critical stages in approved activities are carried out in compliance with the terms and conditions of the Permit. Facility and documentation inspections can happen at any time of the year and tend to be scheduled outside of the growing season. Field trial inspections are usually planned for the growing season and target specific activities such as planting, flowering, harvest and post-harvest periods, although not all of these stages will be inspected for each trial.

Approval to conduct GM activities does not exempt the authorised parties from other regulatory requirements such as phytosanitory aspects.

Inspections may be carried out at any time. The trial or facility manager is required to provide access to the facility, storage area or trial site and to make GMO records available for the purpose of inspections. The NBMA arranges in advance with the Permit Holder a mutually agreed upon time for the visit to the site. The Permit Holder is required to inform the trial or facility manager and other relevant staff at the site of the inspection date and time.

Unannounced inspections may be carried out at any time at the discretion of the NBMA, without prior notification to the Permit Holder or site manager.

Biosafety Inspectors must prepare themselves in advance of any inspection by obtaining the appropriate documents and equipment required to carry out the inspection. The Inspector needs to be properly kitted and be familiar with the activity documents prior to a site inspection or visit such as:

i. A copy of the activity Permit, including the specific terms and conditions from the NBMA;

ii. The site location map from the NBMA;

iii. Contact details for the site manager and/or the Permit Holder;

iv. An inspection form or checklists; a clipboard, notepaper and pens;

v. A copy of the protocol for any activity that will be inspected;

vi. Any additional technical information that may be needed, for example: visual keys for the growth stages of specific crops; lists of pesticides approved for use on the crops to be inspected, etc.;

vii. Previous inspection reports for the site and/the activity to be inspected, if these are available.

The Inspector should inform the Permit Holder of the documentation that must be available for review, such as Permits, SOPs, Guidelines and reporting forms.

In addition to the documents required for any site visit, certain equipment may also be required, depending on the circumstances:

i. A GPS unit;

ii. GPS of the location;

iii. A camera;

iv. Gloves;

v. Sample bags;

vi. Test kits;

vii. A measuring tape to verify isolation distances/ Trackometer;

viii. Inspector's Staff Identity Card;

ix. Transport to and from site;

x. Other equipment or resources at the discretion of the Inspector.

4. THE INSPECTION PROCESS

A site inspection includes the following steps:

i. The NBMA arranges the site visit with the Permit Holder and finds out who will host the inspection at the sites.

ii. Before the inspection, the Inspector clarifies questions concerning the activity and the terms and conditions of the approval with the NBMA. The Inspector also receives guidance on critical hazard points that will need to be reviewed at the site and any history of non-compliance related to the Permit Holder, the site, or similar, previous activities from designated superior Officer of the NBMA.

iii. On arrival at the site, the Inspector conducts a brief meeting with the site manager or Permit Holder, to be updated on progress of the regulated activity and any areas of question or concern.

iv. The Inspector conducts a visual examination of the site, facility or activity and takes note of compliance with requirements, using a relevant Checklist/ form.

v. The Inspector reviews documents and files, noting adherence to the terms and conditions of the Permit including the date.

vi. The Inspector meets with the Permit Holder and/or the site manager and/or other site personnel, if needed, to address any questions or point of clarification.

Note that steps ii, iii, and v may be completed in any order, and each may be repeated as needed

vii. The Inspector completes a draft of the checklist, noting issues of concerns.

viii. The Inspector conducts an exit meeting with the Permit Holder or site manager and points out any findings or areas of concern, answers any questions, and

advises the site manager on follow-up steps and on any upcoming compliance requirements.

ix. In the case of significant findings of non-compliance, the Inspector informs the NBMA immediately, if possible, while still at the site. The NBMA determines an appropriate course of action and communicates the requirements to the Permit Holder.

x. The Inspector completes a report on the inspection and submits it to the NBMA within three working days after the inspection.

xi. All notes, checklists and submitted reports are maintained by the NBMA in secure storage.

Critical elements of inspection of GMO activities are detailed in the following section, and are included in activity-specific checklists/forms found at the end of the Guidelines.

5.0 CRITICAL ASPECTS OF INSPECTIONS

5.1 Facility Inspection

Inspection of facilities and records may be carried out at any time once a facility is registered for GMO activity, either as part of an activity approval, or through a facility registration process. The critical aspects of the facility are:

i. Records for transport of regulated materials;

ii. Storage areas;

iii. Containment measures;

iv. Waste treatment;

v. Training of personnel;

vi. Availability of guidance documents, such as SOPs and;

vii. Common procedure in case of emergency.

Some national regulations may require written risk assessments for contained work with GMOs. Inspectors conduct an examination of the facility and records, taking note of specific requirements in the above areas.

Inspectors should ensure that the following aspects of the facility and records are compliant with the terms and conditions for contained work with GMOs:

i. The facility is approved for contained GM activities;

ii. The staff members are trained and training records are available;

iii. Access and containment measures meet national requirements;

iv. Storage areas are secure, separate and labeled;

v. The movement of GMOs in and out of storage is logged;

vi. All waste GMOs are rendered non-viable prior to disposal;

vii. Guidance documents are available for staff members and are up-to-date;

viii. Activity records are available, when required;

ix. All relevant staff of the facility have the approval document of the facility;

x. Written risk assessments are available when required.

5.2 Transport of GMOs

The critical aspects of compliance with procedures for transport and shipping GMOs are:

i. Maintaining security and control over the material with correct packaging and documented handling;

ii. Maintaining the identity of the GMOs with clear and detailed labeling;

iii. Completing documentation requirements so that security, control and identity of the GMOs may be demonstrated.

Inspectors conduct an examination of the facility and documents in accordance with the terms and conditions for transport and shipping, taking note of the following:

i. Packaging and labeling;

ii. Shipping documentation;

iii. Waste disposal;

iv. The storage area for GMO;

v. Emergency procedure;

5.3 Confined Trials with GMOs

The critical aspects of conduct for a field trial with GMO plants are:

i. Maintaining security and control over the material to and from the trial site;

ii. Maintaining reproductive isolation at the trial site;

iii. Preventing the release of planting materials from the trial site;

iv. Ensuring that GM material does not enter the food and feed chain;

v. Completing documentation requirements so that confinement of the material can be demonstrated.

Inspectors conduct an examination of the trial site and documents to ensure compliance with the terms and conditions of the Permit, taking note of the following:

i. Site security and trial layout;

ii. Measures for reproductive isolation;

iii. Documentation on storage, transport, planting, monitoring, harvest and devitalisation and disposal of waste materials;

iv. Reporting requirements, including corrective action reports.

The critical hazard points in confined trials are identified during the risk assessment process and these are areas that Inspectors focus on when setting priorities for inspection and ensuring that adequate documentation is available. Initially, while there are only a few confined trials, Inspectors may have time to inspect each of these critical hazard points, it will be necessary to focus on spot checks where these are most needed.

5.3.1 Trial protocol

Protocols for trials typically include details that are not directly related to biosafety, but rather to the technical objectives and methodology of the trial, however, compliance with technical instruction is critical to obtaining valid, understandable and useful results, and is thus a legitimate concern of the NBMA and Biosafety Inspectors. Lack of compliance with the trial protocol may be an indicator of deficiencies in other areas, due to lack of personnel, resources or knowledge.

Inspectors conduct an examination of the trial site and documents in accordance with the trial protocol, taking note of the following:

i. Experimental design, plot layout and labeling requirements;

ii. Observation and sampling requirements and methodology;

iii. Trial maintenance and monitoring requirements;

iv. Any other technical requirements found in the trial protocol.

It is not necessary for the Inspector to have access to the data from the trial, only to confirm that data were collected as planned.

5.3.2 Trial implementation

For field trials this is the planting stage, but for other GMOs such as microorganisms for agriculture or clinical trials, this is the first release of the GMO into the environment. The critical hazard points for this activity are maintaining control of the regulated material and ensuring that unused GMOs are destroyed on site, or returned to storage in a secure manner, which includes using the required documentation, packaging and labeling.

5.3.3 Reproductive isolation of trials

This is of particular importance in field trials with GM plants, but is also considered for trials with GM animals. For field trials, one or more of the following may be implemented to control movement of pollen from GM plants on the site to sexually compatible plants around the site:

i. Isolation distance;

ii. Border rows;

iii. Destruction of flowers including the timely removal of sexually compatible plants;

iv. Tenting and bagging;

v. Timing of flowering;

vi. Termination of the trial before flowering;

vii. Physical barriers (vegetation)

Inspections of field are frequently timed to help ensure that the Permit Holder fulfills the requirements for reproductive isolation.

5.3.4 Control of viable material

Trial releases require the use of relatively small quantities of GM material that is viable and is able to grow and possibly reproduce in the released environment. Control of the planting material and viable GMOs is critical to ensure that they do not persist and spread in the released environment after the trial. Inspectors need to consider the following critical activities when reviewing confined trials:

i. Management and control of viable GMOs, including seed and cuttings

ii. Implementation protocols that maintain control of viable GMOs, e.g. access to trial sites, restricted visibility and access distance from public throughways, etc.

iii. Harvest protocols that minimize the distribution of viable GMOs, e.g. small machinery; cleaning machinery, packaging and labeling and documentation of viable material to be removed from the authorised site, etc.

iv. Waste disposal that ensure de-vitalization of GMOs, e.g ploughing or burying for plants, and autoclaving for clinical trials.

5.3.5 Termination of Confined Field Trial

The critical aspects of termination of a confined trial are:

i. Maintaining security and control over the material in the field site;

ii. Preventing the release of planting materials from the trial site;

iii. Appropriate measures for destruction of material in the trial site, or for storage and shipping of any material to be retained;

iv. Completing documentation requirements so that confinement of the material may be demonstrated.

Inspectors conduct an examination of the trial site and documents in accordance with SOP or other requirements, taking note of the following:

i. Procedures employed or to be employed in terminating the trial;

ii. Measures for de-vitalization and disposal of material from the trial;

iii. Documentation and reporting requirements.

5.3.6 Post-harvest management of the trial site

Post-harvest management of a confined trial site applies mostly to GM plants, but is sometimes required for trials with GM microorganisms. The critical aspects of post-harvest management of a confined trial are:

i. Maintaining control over the trial site and how it is used in post-harvest years;

ii. Ensuring that post-harvest use is compatible with the terms and conditions of the approval;

iii. Monitoring for volunteers and destroy these before they flower;

iv. Maintaining records of monitoring and actions taken when volunteers are identified.

Inspectors conduct an examination of the trial site and documents in accordance with terms and conditions of the approval and take of the following:

i. Post-harvest restrictions regarding ways in which the field may be used

ii. Post-harvest monitoring and documentation requirements

5.4 Unintended Release

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

i. Containing the GMOs at the release site;

ii. Timely communication with the NBMA by the Permit Holder;

iii. Removing the GMOs from the site or rendering them non-viable;

iv. Preventing GMOs from being consumed by humans or animals;

v. Preventing GMOs from becoming established and persisting in the environment.

Inspectors 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 NBMA, which will provide specific requirements for such inspections, according to the characteristics of the release.

5.5 Post Commercialization monitoring

This is done after environmental release in other to assess the impact of the identified or unintended risk of GMO on the environment.

5.6 Quality of Data and Records

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.

5.7 Exit Meeting

An exit meeting with the Permit Holder 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 Permit Holder 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.

5.8 Inspection Report

The Inspector completes an inspection report, providing a brief narrative of the inspection, noting any significant findings or areas of concern on the part of the Inspector or site manager, and any follow up actions that are recommended, including recommendations for subsequent inspections. Copies of the completed inspection forms should be attached to the inspection report.

The inspection report should be submitted to the appropriate superior officer within 3 working days after the inspection.

This report follows an established format which contains information on:

i. The date and purpose of the inspection;

ii. The activity's regulatory approval code/No.;

iii. Details of what issues were identified;

iv. What follow up actions are recommended;

v. Issues the NBMA is required to address with the Permit Holder;

vi. The name and signature of the Inspector.

5.9 Responding to Non-compliance

When Inspectors discover non-compliance, they can respond in several ways which is based on:

i. The national regulatory requirements;

ii. The urgency of the situation;

iii. The level of risk to the environment;

iv. How readily corrective action can be implemented;

v. The compliance history of the Permit Holder.

The Permit Holder must carry out any corrective action where the risk to the environment and human health is real and imminent and must submit a corrective action report when the issue has been resolved. The NBMA will determine whether a second inspection is needed of that facility. The NBMA may change the terms and conditions of the approval based on the corrective action, if it is not already included as an alternative risk management measure for the activity.

6. MODEL FORMS FOR INSPECTIONS

Model forms used for the inspection of specific GMO event or facility are attached as Annexes 1 – 12.

ANNEX 1: PLANTING INSPECTION FORM OF GENETICALLY MODIFIED ORGANISM UNDER CONFINED FIELD TRIAL

National Biosafety Management Agency
NBMA
Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Type of GMO: _____ **Permit number:** _____

Duration of Permit: _____

Inspection No: _____

Site Name: _____

Date of inspection: _____ **Name and Designation of Personnel Seen at site:** _____

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit required and reason /timing
I <u>GENERAL</u> 1. Site plan seen		
2. i. Does the Release Site Manager have a copy of the approval document? ii. Does he/she understand the duties through a set of clear instructions from the approval document holder?		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit required and reason /timing
3. Is there an effective management chain from applicant/approval document Holder to Release Site Manager?		
4. List the management chain. If leasing arrangements exist, does it cover the complete Release Site and/or the complete period of release?		
II. <u>RELEASE SITE</u> 5. Does the Release Site correspond to the data notified under the approval document; No and size of plots (state)? E.g. 100 plots of 4M x 25M		
6. Is the Release Site clearly identifiable, - This season? - In subsequent monitoring seasons? - State how it is/will be identifiable		
III. <u>SOWING/PLANTING</u> 7. Was there liaison with the NBMA concerning sowing/planting dates? 8. Planting date		
9. Does the sowing/planting comply with the conditions of the Permit - Type of GMO released? - Number of seeds/plants? - Transport of seeds/plants? - Labeling of seeds/plants? - Seed/plant lot number To be checked visually and/or with site manager, if possible		
10. Have isolation measures specified in the Permit been implemented? Isolation distance from non-GMO crops of relevance: Border rows/pollen barriers planted?		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit required and reason /timing
Width ……. -Is the site secured? -Are there information signs posted on all 4 sides of the trial site?		
11. Has the use and cleansing of machinery/equipment been appropriate and according to the conditions of the Permit?		
12. What happens to spare GMO seeds/plants? - Storage? - Disposal?		
III <u>OTHER COMMENTS ETC</u> (*Continue on further sheet if necessary*) -Are there completed material transfer forms maintained at the CFT site which will be available at all times for review by NBMA Inspectors? - Is there a CFT compliance manual developed? - Are there reports of accidentally removed GM seeds/plants from the storage site before planting? -Is a follow up visit advised with another Inspector? -Any samples taken? (record details) -Any photographs taken? (record details) -Were any documents received/obtained? Type of documents received/obtained (if any) -Signed for and receipt issued? -Is there evidence to show that the CFT staff are properly trained		

Attach any maps, notes etc. to this form and file in appropriate inspection file.

Signature of Inspector: _____

Name of Inspector: _____ Date: _____ Time: _____

ANNEX 2: GROWTH/ FLOWERING STAGE INSPECTION FORM OF GENETICALLY MODIFIED PLANT UNDER CONFINED FIELD TRIALS

National Biosafety Management Agency
NBMA

Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Type of GMO: _____ **Permit number:** _____

Duration of Permit: _____

Inspection No: _____

Site Name: _____

Date of inspection: _____ **Name and Designation of Personnel Seen at site:** _____

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
I <u>GENERAL</u> 1. Site plan seen		
2. i. Does the Release Site Manager have a copy of the approval document? ii. Does he/she understand the duties through a set of clear instructions from the approval document holder?		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
3. Is there an effective management chain from applicant/approval document Holder to Release Site Manager?		
4.List the management chain. If leasing arrangements exist, does it cover the complete Release Site and or the complete period of release?		
II. <u>PLANT GROWTH/ FLOWERING STAGE</u> State growth stage at date of visit 5. Is the border row/pollen barrier , trap of the GM crops / plant around the CFT plot effective (where applicable), as shown by: - Correct width? - Sufficiently established and flowering by the time the GM crop starts flowering? State pollen barrier growth stage		
6. Has the removal of flowering GM plants been effective (where applicable) as evidenced by: - Regular removal? - Correct disposal, in accordance with consent conditions?		
7. Can the GM plot be adequately identified and separated from other crops e.g. barrier rows?		
8. Has the minimum distance between the GM crop and other non-GM crops of relevance been maintained?		
9. If there are fields of livestock next to trial, is the fencing, etc. secure?		
10. Is the isolation zone adequately monitored and any potential hybridization partners removed?		

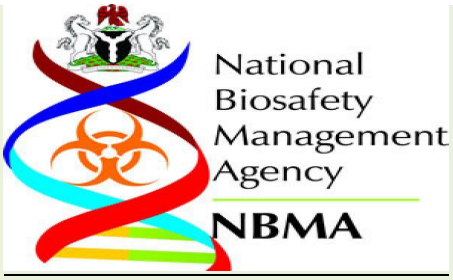
Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
III <u>OTHER COMMENTS ETC</u> 11.Any sabotage/damage to trial? -Any suspicion of a breach of Permit terms and conditions - Are there reports of accidentally removed GM Plants from the trial site after planting? -Is a follow up visit advised with another Inspector? -Any samples taken? (record details) -Any photographs taken (record details) - Were any documents received/obtained? -Type of documents received/obtained (if any) -Signed for and receipt issued? -Is there evidence to show that the CFT staff are properly trained?		

Attach any maps, notes etc. to this form and file in appropriate inspection file.

Signature of Inspector: _____

Name of Inspector: _____ Date: _____ Time: _____

ANNEX 3: FACILITY INSPECTION FORM



Federal Republic of Nigeria

Name /Type of Facility:_____

Facility address (Location):_____

E-mail Address: _____

Tel.No._____

Name of GMO/Type of facility:_____

Permit Code Number(s), if any:_____

Manager:_____

Inspector:_____

Date of inspection:_____

FACILITY

Tick Yes or No in the appropriate box, or not 'NA' = Not Applicable	**YES**	**NO**	**NA**
Is the facility secured from unauthorised access?			
Is the approval document for the facility available?			
Is there sufficient space for the facility to be kept clean and tidy?			
Comments:			

STORAGE AREA			
Is the storage facility labeled and secured from unauthorized access?			
Are GMOs and non-GMOs kept separate in the storage area?			
Is there a pest control procedure in place in the storage area?			
Is the inventory list available and kept current for GMO movement in and out of storage?			
Comments:			

PERSONNEL			
Are all personnel trained in the regulatory requirements for confinement?			
Is there a record and staff training in the biosafety file for the facility?			
Are the biosafety SOPs current and accessible to all staff members?			
Comments:			
WASTE DISPOSAL			
Is there a procedure for disposal of GMOs at the facility?			
Is this sufficient to ensure that live GMOs are not released unintentionally?			
Is waste water treated?			
Comments:			
EXPERIMENTAL RECORDS			
Are records kept of the GMOs used and produced on site?			
Are written risk assessments available, if required?			
Comments:			

INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**

ANNEX 4: SHIPPING AND STORAGE INSPECTION FORM FOR GENETICALLY MODIFIED ORGANISM

National Biosafety Management Agency
NBMA

Federal Republic of Nigeria

Name of Permit Holder: _____

Address:_____

E-mail Address: _____

Tel. No.:_____

Type of GMO:

Storage Site Identification:	
Permit Code Number(s):	**Site Manager:**
Inspector:	**Date of Inspection:**

PACKAGING AND LABELLING			
Unless otherwise noted, Tick Yes or No in the appropriate box, or 'NA' = Not Applicable	**YES**	**NO**	**NA**
Are the packaging layers sufficient for the material?			
Are different GMOs sufficiently separated in the package to prevent mixing?			
Is each layer of packaging labeled as required? Is the quantity/No. of GMO packed complete on receipt?			
If the packaging has not been retained, has Permit for disposal been documented?			
How was the packaging disposed of?			
Comments:			

SHIPMENT DOCUMENTATION			
Are all shipping forms adequately completed, signed and dated?			
Are copies of all shipping documents available in the trial file?			
Comments:			

STORAGE AREA			
Is the storage area restricted to personnel only and is it secure?			
Is the area sign-posted according to requirements?			

Are GMOs kept separate from non-GMOs?			
Are GMOs clearly identified?			
Is there an inventory list available in the storage area for GMO movement and is it current?			
Comments:			

INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**

ANNEX 5: GENERAL INSPECTION FORM OF GENETICALLY MODIFIED ORGANISM UNDER CONFINED FIELD TRIAL

National Biosafety Management Agency
NBMA

Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Type of GMO: _____

Permit number: _____

Duration of Permit: _____

Inspection No: _____

Holder of Approval document: _____

Site Name: _____

Date of inspection: _____

Name and Designation of Personnel Seen at site: _____

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
I <u>GENERAL</u>		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
1. Site plan seen		
2. i. Does the Release Site Manager have a copy of the approval document? ii. Does he/she understand the duties through a set of clear instructions from the approval document holder?		
3. Is there an effective management chain from applicant/approval document Holder to Release Site Manager?		
4. List the management chain. If leasing arrangements exist, do they cover the complete Release Site and/or the complete period of release?		
III. <u>RELEASE SITE</u> 5. Does the Release Site correspond to the data notified under the approval document? Number and size of plot(s) e.g. 100 plots of 4M x 25M		
6. Is the Release Site clearly identifiable, - This season? - In subsequent monitoring seasons? - State how it is/will be identifiable		
IV. <u>SOWING/PLANTING</u> 7. Was there liaison with NBMA concerning sowing/planting dates? i. Planting date		
8. Does the sowing/planting comply with the conditions of		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
the Permit - Type of GMO released? - Number/Weight of seeds/plants? - Transport of seeds/plants? - Labeling of seeds/plants? - Seed/plant lot number To be checked visually and/or with site manager, if possible		
9. Have isolation measures specified in the Permit been implemented? Isolation distance from non-GMO crops of relevance (state): Border rows/pollen barriers planted? Width… -Is the site secured? -Are there information signs posted on all 4 sides of the trial site?		
10. Has the use and cleansing of machinery/equipment been appropriate and according to the conditions of the Permit?		
11. What happens to spare GMO seeds/plants? - Storage? - Disposal?		
V. <u>PLANT GROWTH STAGE</u> State growth stage at date of visit 12. Is the border row/pollen barrier, trap of the GM crops / plant around the CFT plot effective (where applicable), as shown by: - Correct width? - Sufficiently established and flowering by the time the GM crop starts flowering? State pollen barrier growth stage		
13. Has removal of flowering GM plants been effective (where applicable) as evidenced by: - Regular removal? - Correct disposal, in accordance with consent conditions?		
14. Can the GM plot be adequately identified and separated from other crops e.g. barrier rows?		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
15. Has the minimum distance between the GM crop and other non-GM crops of relevance been maintained?		
16. If there are fields of livestock next to trial, is the fencing, etc. secure?		
17. Is the isolation zone adequately monitored and any potential hybridization partners removed?		
VI. <u>HARVEST/POST HARVEST</u> 18. Has there been good liaison with NBMA concerning harvest times?		
19. Has there been effective removal of the GM crop? - Harvest? - Any pre-harvest treatments e.g. Desiccant or destruction used? - Destruction of harvested material? e.g. incineration, autoclaving, deep burial - storage/ transport of harvested material e.g. ships/lorries, etc. secure? - Any samples removed by company for laboratory use?		
20. Has there been effective post-harvest management? - Herbicide spraying? - Rotavation? - Incineration?		
21. Has the machinery/equipment used for harvest and other post-harvest activities been effectively cleansed?		
VII. <u>POST-TRIAL MONITORING AND CONTROL</u> 22. Is there a regular monitoring program of the release site with maintenance of an appropriate log book?		
23. Is the planting regime correct following the GM crop?		

Item	Accordance with Permit terms and conditions Yes/No/Not Applicable	Inspector's comments and recommendations State if further visit is required and reason /timing
24. Has there been effective control of any volunteers detected on the site? Record if any volunteers have been detected. Give number		
25. Are there any problems in detecting volunteers due to the type of crop grown in the following season?		
VIII <u>OTHER COMMENTS ETC</u> 26. Any sabotage/damage to trial? -Any suspicion of a breach of Permit terms and conditions? (*Continue on further sheet if necessary*) -Are there completed material transfer forms maintained at the CFT site and will be available at all times for review by Nigerian biosafety Inspectors and regulators. - Is there a CFT compliance manual developed? - Are there reports of accidentally removed GM Plants from the trial site after planting? -Is a follow up visit advised with another Inspector? -Any samples taken? (record details) -Any photographs taken (record details) - Were any documents received/obtained? -Type of documents received/obtained (if any) -Signed for and receipt issued? -Is there evidence to show that the CFT staff are properly trained?		

Attach any maps, notes etc to this form and file on appropriate inspection file.

Signature of Inspector: _____

Name of Inspector: _____ Date: _____ Time: _____

ANNEX 6: CONFINED FIELD TRIAL PROTOCOL INSPECTION FORM

Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Type of GMO: _____

Permit number: _____

Duration of Permit: _____

Inspection No: _____

Site Name: _____

Date of inspection: _____

Name and Designation of Personnel Seen at site: _____

CONFINED FIELD TRIAL PROTOCOL INSPECTION FORM			
Trial Site Identification:			
Permit Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL DESIGN AND INITIATION			
Tick Yes or No in the appropriate box, or 'NI' = Not Inspected	**YES**	**NO**	**NA**
Do the trial site layout and experimental design agree with the trial protocol?			
Do the plots, plot layout and experimental design meet the requirements of the Study Plan?			
Are the site labels present, clear and do they meet requirements?			
Do buffers, borders and security meet requirements?			
DATA COLLECTION AND SAMPLING			

Have all data been collected to date, according to the approved methodology?			
Has approved sampling been carried out according to the approved methodology?			
Has any storage, transportation or analysis of samples been carried out according to the approved methodology?			
Have all reporting requirements been submitted to the NBMA?			
Comments:			

COMPLIANCE WITH OTHER INSTRUCTIONS (LIST SPECIFIC INSTRUCTIONS, ACCORDING TO TRIAL)

INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**

ANNEX 7: CONFINED FIELD TRIAL TERMINATION/ HARVEST INSPECTION FORM

Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Name of GM Crop: _____

Permit number: _____

Duration of Permit: _____

Inspection No: _____

Site Name: _____

Date of inspection: _____

Name and Designation of Personnel Seen at site: _____

CONFINED FIELD TRIAL TERMINATION/ HARVEST INSPECTION FORM			
Trial Site Identification:			
Permit Number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TERMINATION OF THE TRIAL			
Unless otherwise noted, tick Yes or No in the appropriate box, or 'NA' = Not Applicable	**YES**	**NO**	**NA**
Was the NBMA notified at least five (5) days prior to termination or harvest?			
Are measures for cleaning equipment and personnel numbers adequate to prevent the off-site movement of viable GMO materials?			
Are any GMOs to be retained?			

If yes, has the retention of GM material from the trial been approved by NBMA?			
Do measures for packaging, labeling and transport meet the NBMA requirements?			
Is any non-viable GM material to be moved off-site for disposal?			
DE-VITALIZATION AND DISPOSAL			
Are the measures in place for on-site disposal adequate?			
Describe measures for on-site disposal or de-vitalization:			
Comments:			
RECORDS AND REPORTS			
Has trial termination report been completed and submitted to the NBMA? **DATE SENT:**			
Comments:			

INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**

ANNEX 8: TRIAL POST-HARVEST INSPECTION FORM

Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Name of GM Crop: _____

Permit number: _____

Duration of Permit: _____

Inspection No: _____

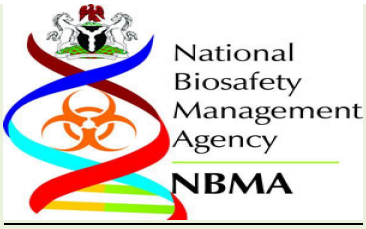
Site Name: _____

Date of inspection: _____

TRIAL POST-HARVEST INSPECTION FORM			
Trial Site Identification:			
Permit Number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
POST HARVEST RESTRICTIONS			
Unless otherwise noted, tick Yes or No in the appropriate box, or 'NA' = Not Applicable	**YES**	**NO**	**NA**
Does this crop meet the regulatory requirements?			
Does the Permit Holder retain control over the trial site for the post-harvest period?			
Are measures in place to prevent grazing on the land, if this is a requirement?			
Is post-harvest monitoring being carried out and documented according to requirements?			
Are volunteers being destroyed and disposed of according to the requirements?			
List measures for destruction and disposal of volunteers in place:			
Are measures in place for cleaning equipment that are used to destroy volunteers?			

COMMENTS:	
INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**

ANNEX 9: TRIAL RECORD REVIEW AND EXIT MEETING INSPECTION FORM



Federal Republic of Nigeria

Name of Permit Holder: _____

Address: _____

E-mail Address: _____

Tel. No.: _____

Type of GM Crop: _____

Permit number: _____

Duration of Permit: _____

Inspection No: _____

Site Name: _____

Date of inspection: _____

TRIAL RECORD REVIEW AND EXIT MEETING INSPECTION FORM			
Trial Site Identification:			
Permit number:	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL RECORDS AND FILES			
Tick Yes or No in the appropriate box, or 'NI' = Not Applicable	**YES**	**NO**	**NA**
Are copies of guidelines, SOPs, terms and conditions of Permit and other relevant documents readily available to the trial personnel?			
Are trial records and files organized and stored in a secured area?			
Are trial records and files readily available to trial personnel?			
Are trial records and files complete and up-to-date?			
Are adequate recording standards being maintained?			
Have all required reports been submitted promptly?			
Are copies of all reports included in the trial files			
COMMENTS:			
INSPECTOR'S SIGNATURE:	**DATE:**		
TRIAL MANAGER'S SIGNATURE:	**DATE:**		

ANNEX 10: UNINTENDED RELEASE AND NON-COMPLIANCE INSPECTION FORM

Federal Republic of Nigeria

Name of Permit Holder: _____
Address: _____
E-mail Address: _____
Tel. No.: _____
Name of GM Crop: _____
Duration of Permit: _____
Inspection No: _____
Site Name: _____

Trial Site Identification:	
Permit Number(s):	**Trial Manager:**
Inspector:	**Date of Inspection:**

UNINTENDED RELEASE OR NON-COMPLIANCE

Unless otherwise noted, tick Yes or No in the appropriate box, or 'NA' = Not Applicable	**YES**	**NO**	**NA**
Was any unintended release recorded?			
Was any non-compliance incident recorded?			
Where required, was the incident reported to NBMA?			
Has corrective action been taken in accordance with the requirements?			
Describe the corrective action taken:			
Are additional follow-up measures to be carried out?			
If yes, describe:			
COMMENTS:			

INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**

ANNEX 11: INSPECTION REPORT

Federal Republic of Nigeria

Name of Permit Holder: _____
Address: _____
E-mail Address: _____
Tel. No.: _____
Name of GM Crop: _____
Duration of Permit: _____
Inspection No: _____
Site Name: _____

Trial Site Identification:	
Permit Number(s):	**Trial Manager:**
Inspector:	**Date of Inspection:**

GROWTH STAGE OR TRIAL STATUS AT TIME OF INSPECTION

BRIEF NARRATIVE OF THE INSPECTION (ATTACH ADDITIONAL PAGES IF NEEDED)

ITEMS OF CONCERN, UNANSWERED, OR REQUIRING RE-INSPECTION

Item	Re-Inspection? (Y/N)

Comments:

CONCERNS OF TRIAL MANAGER AND/OR INSPECTOR

Follow-up Action	**Responsibility**	**Target Date**	**Re-Inspections (Y/N)**
Comments:			

INSPECTOR'S SIGNATURE:	**DATE:**
TRIAL MANAGER'S SIGNATURE:	**DATE:**
Date Submitted:	

ANNEX 12: Inspection Checklist for Physical Biosafety Containment Facility Level 2 Plant Facility

National Biosafety Management Agency
NBMA
Federal Republic of Nigeria

Guidelines for Certification of a Physical Biosafety Containment Level 2 Facility

Please Note

- This proforma is based on the requirements of certification of *a Physical Biosafety Containment Level 2 Facility*.

Facility and fitting requirements				
		Yes	**No**	**Notes/Details**
Facility	Fully enclosed space bounded by walls, doors, windows, floors and ceilings			
Facility boundaries	Maintained to be rigid, durable and suitable for the environmental conditions they are exposed to, and able to withstand expected wear and tear			
	Transparent sections are made of glass, polycarbonate sheeting or similar durable material			
	Boundaries are impact resistant or protected from impact			

	Entry of surface run off water prevented			
Anteroom	Facility has an anteroom and entry to the facility is via the anteroom			

- If, in answer to any of the questions below, it is indicated that the facility does not meet the requirements of certification or may not be able to meet the expected conditions of certification, then this information should be reported under section 3 of the *Application for the Certification of a Physical Biosafety Containment Facility* along with any suggested strategies to enable certification of the facility.

Organisation name:	
Facility name:	
Inspector's Name:	
	Date:

		Yes	**No**	**Notes/Details**
Decontamination of hands	Washbasin fitted **OR**			
	Other means of decontamination of hands			
Drainage exits	Fitted with barriers to prevent arthropods, animals or GM plants or GM propagative plant material entering or escaping via the drains			
Dealings involving GM micro-organisms (these requirements must also be met if any of the dealings in the facility are to involve GM micro-organisms)				
Surfaces	Smooth, impermeable to water, cleanable and resistant to damage by cleaning agents used in the facility			

Open spaces under benches and equipment	Accessible for decontamination			
Drainage exits	Fitted with liquid traps that are permanently filled with appropriate decontaminant **OR**			
	Liquid entering drains contained and treated as waste			

		Yes	**No**	**Notes/Details**
Aerosol containment	PC2 GM dealings proposed will produce aerosols			
Backflow prevention	Device or system that may cause contamination of a potable water supply with GMOs requiring PC2 containment connected directly or indirectly to any part of a water service			
	If yes - Backflow risk assessment has been carried out			
	Backflow prevention necessary and prevention measures implemented.			
Capacity to comply with certification conditions				
Capacity to comply	Demonstrated capacity to comply with the conditions of certification that will generally be applied to a certified PC2 Facility			

Signature of Inspector:	Date:
Name of Inspector:	
For further information, contact: [The Director General/CEO , National Biosafety Management Agency, National Park Service Along Umaru Musa Yar'adua Way, Near City Gate, Abuja. add official email	