SWAZILAND BIOSAFETY INSPECTION MANUALS AND CHECKLISTS

UNEP

SWAZILAND ENVIRONMENT AUTHORITY (SEA)

GEF

JUNE 2017

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BCH	BIOSAFETY CLEARING HOUSE
CBD	CONVENTION OF BIOLOGICAL DIVERSITY
CFT	CONFINED FIELD TRIALS
CPB	CARTAGENA PROTOCOL ON BIOSAFETY
DNA	DEOXYRIBO NUCLEIC ACID
GE	GENETICALLY ENGINEERED
GEF	GLOBAL ENVIRONMENT FACILITY
GM	GENETICALLY MODIFIED/GENETIC MODIFICATION
GMO	GENETICALLY MODIFIED ORGANISM
GPS	GLOBAL POSITIONING SYSTEM
LMO	LIVING MODIFIED ORGANISMS
NBAC	NATIONAL BIOSAFETY ADVISORY COMMITTEE
NBCH	NATIONAL BIOSAFETY CLEARING HOUSE
SEA	SWAZILAND ENVIRONMENT AUTHORITY
SOP	STANDARD OPERATING PROCEDURES
UNEP	UNITED NATIONS ENVIRONMENT PROGRAMME

1. Introduction

The Kingdom of Swaziland is a Party to the Convention on Biological Diversity (CBD) and subsequently to the Cartagena Protocol on Biosafety (CPB). As such the Kingdom enacted the Biosafety Act in 2012 following an extensive process of developing the National Policy entitled "Creating an enabling environment for the safe use of biotechnology and its products in Swaziland" and putting into place the National Biosafety Framework. The major objective of the Biosafety Act, 2012 is to ensure an adequate level of protection in the field of safe transfer, handling and use of (GMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account human health. The Biosafety Act, 2012 (Section 31) amongst other things advocates for the appointment of public officers as Biosafety Inspectors to ensure compliance with the dictates of the Act and its regulations.

During the period 2013 to 2017 the Kingdom implemented the National Biosafety Framework with the support of the Global Environment Facility (GEF) and the United Nations Environment Programme (UNEP). During the implementation of this 4 year project, the country's Environmental Health Officers from the Ministry of Health were designated as Biosafety Inspectors through an agreement forged between the Swaziland Environment Authority and the Ministry of Health.

The Environmental Health Officers received some introductory training in Modern Biotechnology and Biosafety during the project period. In order to improve their effectiveness in the monitoring of genetically modified organisms and in the enforcement of the Biosafety Act, 2012 it became necessary to develop inspection manuals and checklists and conduct training for them. In addition to the Environment Health Officers, the Environment Inspectors within SEA and the Swaziland Revenue Authority (Customs Department) would receive similar training. The role of Border Control Officers is crucial because trade in environmental sensitive products such as LMOs is a growing global challenge. There is need for international cooperation to monitor and control the cross-border movement of such products in order to protect the environment and human health. This is particularly so for Swaziland whose major

trading partner, the Republic of South Africa, has commercialized the GM technology. It is critical that inspectors are well trained in the procedures for inspections and in how to respond when non-compliance is identified.

This manual is intended as a resource for biosafety regulatory inspectors and others designated by the Swaziland Environment Authority which is the Biosafety Competent Authority, to check compliance with regulatory requirements for GMO import/export, contained use (laboratories, confined trial sites etc.), intentional introduction into the environment other than placing on the market, GMOs for food, feed and processing, and unintentional introduction into the environment. The manual provides instructions for biosafety inspections for carrying out compliance evaluations on all regulated biosafety activities. Typically, inspectors will be provided with specific training in all aspects of biosafety compliance for all the activities regulated nationally. It is the responsibility of the applicant to ensure compliance with the terms and conditions of authorization, and Biosafety Inspectors undertake to check the level of compliance when they investigate a specific facility or activity.

1.1. Terminology Used in this Manual

This section explains terminology used in this manual as it is important for the Inspectors to be familiar with it to enable them to know the basis, exact meaning and interpretation of terms and conditions related to regulated activities, so they will be able to provide answers and clarity that are founded on the regulatory policy of Swaziland.

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

Authorised Party: The individual or institution that receives 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 Control Officers: Specialized government agencies or personnel who control the movement of people, animals and goods into as well as out of a country.

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 requirements of all of the terms and conditions of authorization.

Confined Field Trial (CFT): A field trial of GM plants not approved for general release, in which measures for reproductive isolation and material confinement are enforced in order to confine 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 (n**):** A segment of DNA to be transferred into a cell using recombinant DNA technology.

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

Facility Manager: The individual responsible for the 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 organisms 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.

Introduction into the Environment: Refers to the commercializing stage, where GMO go beyond confined use and are planted at uncontrolled scales by farmers.

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.

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

Reproductive 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 an authorised party 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.

Temporal 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 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 an confined trial. 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 fields during subsequent growing seasons.

Working hours: Working hours refer to the period between 08:00 and 17:00, which are the official working hours in Swaziland.

1.2. Purpose of the Manual

The purpose of this manual is to provide instruction and guidance to biosafety regulatory inspectors in accordance with the Act. Inspection and oversight of regulated GMO activities in Swaziland serves the following purposes:

a) To assess and verify compliance with the terms and conditions of authorization from the Competent Authority.

b) To determine if contained facilities used for research, storage and production of GMOs comply with regulatory requirements for containment.

c) To provide guidance to border control officers in the control of cross-border movement of LMOs/GMOs.

d) To ensure that the requirements of data quality and integrity are met.

e) To provide opportunities to increase awareness of authorised parties and site managers with the regulatory requirements, thus helping to ensure continuing biosafety.

f) To answer questions and provide clarification to managers and authorised parties on regulatory requirements.

g) To encourage authorised parties to ensure that regulatory requirements are met. This helps foster self-regulated compliance and advances the goal of continued and safe utilization and testing of GMOs.

This manual provides a basis for a logical and step-wise approach to preparing for the inspection, conducting the inspection of the site and documentation, interviewing personnel for pertinent information, obtaining necessary confirmation of key information, writing the inspection report, notifying the regulatory authority of the inspection findings and recommendations, and implementing any corrective action that may be required.

Strict adherence to procedures and the regulatory requirements for activities with GMOs is critical to safeguarding the environment, and preventing any regulated material from entering the food or feed chain.

2. Authorisation and Training

Inspectors enter facilities and trial sites under the authorisation of the Biosafety Act, 2012 and Environmental Management Act, 2002 (Section 60), among other laws, enabling the regulation of specific activities. These laws give regulatory inspectors the right to enter premises and seize materials, if this is necessary. However, most inspections are undertaken with prior warning to the authorised party and with the full cooperation of the authorised party and site manager.

When approval is given for an activity with a GMO, the National Biosafety Advisory Committee (NBAC) may identify key activities that should be inspected and the regulatory office needs to set priorities for inspections based on these recommendations. Often the NBAC will identify 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 Swaziland Environment Authority (as the Competent Authority) has the option to identify other Regulatory agencies in departments of agriculture, customs, health and environment that have existing inspectorates with inspectors who already have legal training and/or inspection rights. These inspectors would need training in biosafety and basic biotechnology to equip them for inspection of GM activities. The Competent Authority should then ensure that there is 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 that will require inspection.

2.1. Skills Required for Biosafety Inspection

Before designating Biosafety Inspectors, they need to be trained in four types of skills:

a) Legal (Understanding the Biosafety Act, 2012)

b) Technical

c) Organisational

d) Personal.

Legal skills usually come through legal training and/or qualification as officers of law in the country or through relevant workshops. Technical skills include a good understanding of ecology, general biology, molecular biotechnology and gene transfer, a 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. In addition, inspectors require personal qualities that give them credibility to do their job. These qualities include trustworthiness, non-corruptibility, 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 interests.

On-the-job training for Biosafety Inspectors means that the SEA may need to work closely with the Biosafety Inspectors until they understand the processes and procedures well. The SEA should develop inspection guidelines so that the inspectors can proceed without accompaniment. Bearing in mind that the number of GMO trials is usually small at the start, and grows relatively slowly, it is seldom necessary to start with a large inspectorate.

3. Preparing for an Inspection

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

Importantly, approval to conduct GM activities does not exempt the authorised parties from other regulatory requirements such as phytosanitary aspects. Many Biosafety Inspectors will also assess compliance with other regulations under their jurisdiction.

Inspections may be carried out at any time during working hours. 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 inspection. The inspector should arrange in advance with the authorised party a mutually agreed upon time for the visit to the site. The authorised party should inform the trial or facility managers and other relevant staff at the site of the inspection date and time.

Sometimes an unannounced inspection is undertaken. These will be carried out at any time at the discretion of the SEA without prior notification to the authorised party 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 assemble and be familiar with the activity documents prior to a site inspection or visit, such as:

a) A copy of the activity authorisation, including the specific terms and conditions. These should be provided by the Biosafety Registrar's office, the NBCH and the BCH

b) The site location map

c) Contact details for the site manager and/or the authorised party

d) An inspection form or checklists; a clipboard, notepaper and pens

e) A copy of the protocol for any activity that will be inspected

f) 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*.

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

The inspector should inform the authorised party of the documentation that must be available for review, such as authorization letters or permits, SOPs, guidelines and reporting forms.

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

a) A GPS unit
b) A camera
c) A measuring tape to verify isolation distances
d) Inspector's credentials (if not personally known to the Party or Trial Manager)
e) Transport to/from the site

f) Other equipment or resources at the discretion of the Inspector.

4. The Inspection Process

4.1 The site inspection should include the following steps:

1. Inspectors familiarize themselves with the biosafety requirements of the regulated activities and the technical aspects of the work.
2. The inspector arranges the site visit with the authorised party and finds out who will host the inspection at the site.
3. Before the inspection, the inspector clarifies questions concerning the activity and the terms and conditions of the approval with the regulatory authorities. 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 Authorised Party, the site, or similar, previous activities.
4. On arrival at the site, the Inspector conducts a brief meeting with the site manager or authorised party, to be updated on progress of the regulated activity and any areas of question or concern.
5. The Inspector conducts a visual examination of the site, facility or activity and takes note of compliance with requirements, using a checklists or form.
6. The Inspector reviews documents and files, noting adherence to the terms and conditions of the approval including the data quality.
7. The Inspector meets with the Authorised Party and/or the Site Manager and/or other Site Personnel, if needed, to address any questions or points of clarification.

Note that steps 3, 4, and 5 may be completed in any order, and each may be repeated as needed.

8. The Inspector completes a draft of the checklists, noting any concerns or issues.

9. The Inspector conducts an exit meeting with the authorised party 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.
10. In the case of significant findings of non-compliance, the Inspector informs the regulatory authority immediately, if possible, while still at the site. The regulatory authority determines an appropriate course of action and communicates the requirements to the authorised party.
11. The Inspector completes a report on the inspection and forwards it to the regulatory authority within three working days after the inspection.
12. All notes, checklists and submitted reports are maintained by the Inspector in secure storage for the duration of the authorisation.

4.2 The Inspection for Customs and Border Control Officers should include the following steps:

1. The documentation that accompanies a shipment that contains LMOs/GMOs must identify the shipment as such

2. Imports, exports and transit shipments of LMOs/GMOs have to accompanied by an “Import Permit” issued by the Swaziland Environment Authority and an “Export Permit” issued by the exporting country.

3. These permits should be accompanied by a “National Agricultural Marketing Board Permit” in the case of scheduled products (maize grain, maize grits, soya beans, crushed soya beans).

4. For commodities such as cotton seed, there should be a permit from the Swaziland Cotton Board in the documentation.

5. In the event that an import, export or transit shipment is claimed to be “Non-GMO”, evidence should be provided by producing a “Non-GM Certification”.

6. Where Customs and Border Control Officers suspect that a shipment is GM positive, yet the Non-GM certification has not been produced, the Inspector can verify by sampling and testing for genetic modification using the Spot-Kits provided by SEA, and follow that up sending

samples (through SEA) to be further tested at the GM Detection Laboratory at UNISWA, Faculty of Agriculture.

Critical elements of inspection of GMO activities are detailed in the following section, and are included in activity-specific checklists found at the end of the manual. Checklists should be adapted to meet the specific requirements of national regulations.

5. Critical Aspects of Inspections

5.1. Facility Inspection

Inspection of the facility 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 (as guided by the Biosafety Regulations). The critical aspects of the facility are:

a) Records for transport of regulated materials,

b) Storage areas,

c) Containment measures,

d) Waste treatment and residue destruction,

e) Training of personnel,

f) Availability of guidance documents, such as SOPs and

g) Summary of all activities on storage site (storage site inventory).

The Biosafety Regulations require written risk assessments for contained work with GMOs or any other GMO related activity. Inspectors conduct an examination of the facility and records, taking note of specific requirements in the above areas.

5.1.1 Critical aspects of facility and records

In particular, inspectors should ensure that the following aspects of the facility and records are compliant with the terms and conditions as per the issued permit:

a) The facility is approved for contained GM activities,

b) The staff members/Farmers are trained and training records are available,

c) Access and containment measures meet permit conditions,

d) Storage areas are secure, separate and labelled. The movement of GMOs in and out of storage is logged,

e) All waste GMOs are rendered non-viable prior to disposal,

f) Guidance documents are available for Farmers/staff members and are up-to-date,

g) Activity records are available, when required,

h) Written risk assessments are available when required,

i) Any other compliance condition stated on the decision document or in the application.

5.2. Transport of GMOs

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

a) Maintaining security and control over the material with correct packaging and documented handling procedures

b) Maintaining the identity of the GMOs with clear and detailed labelling

c) Having the GMO documentation at all times so that security, control and identity of the GMOs may be demonstrated.

5.2.1 Critical aspects for Transport of GMOs

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

a) Packaging and labelling

b) Shipping documentation

c) Emergency response measures

d) The storage area for GMO and separation from any other non-GM material to prevent mingling of the consignments.

5.3. Confined Trials with GMOs

The critical aspects of conduct for a GM field trial are:

a) Preventing public access of the trial site,

b) Maintaining reproductive isolation at the trial site which could include fencing and or notices,

c) Preventing the release of planting material from the trial site,

d) Ensuring that GM material does not enter the food and feed chain,

e) Completing documentation requirements so that confinement of the material can be demonstrated,

f) Disposal or destruction of all residual material,

5.3.1 Critical aspects for confined field trial with GMOs

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

a) Site security and trial layout

b) Measures for reproductive isolation

c) Documentation on storage, transport, planting, weeding, monitoring, flowering, harvest, devitalisation and disposal of waste materials

d) 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 will 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, but in time it will be necessary to focus on spot checks where these are most needed.

5.3.2 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 instructions is critical to obtaining valid, understandable and useful results, and is thus a legitimate concern of the regulatory authority 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:

a) Experimental design, plot layout and labelling requirements

b) Observation, sampling requirements and methodology

c) Trial maintenance and monitoring requirements

d) 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 the data were collected as planned.

5.3.3. Trial implementation

This refers to the planting stage, but for other GMOs such as microorganisms for agriculture 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 shipped back to storage in a secure manner, which includes using the required documentation, packaging and labeling.

5.3.4. 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 pants on the site to sexually compatible plants around the site:

a) Isolation distances, including the timely removal of sexually compatible plants
b) Border rows - growing non-GM plants around the trial to trap pollen movement
c) Destruction of flowers – to prevent the production of functional flowers
d) Tenting and bagging – to prevent pollen movement by pollinating agents
e) Timing of flowering – to avoid flowering at the same time with other compatible plants
f) Termination of the trial before flowering.

Inspections of field trials should be frequently timed to help ensure that the authorised party fulfills the requirements for reproductive isolation.

5.3.5. Control of viable material

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

a) Management and control of viable GMOs, including seed and cuttings
b) Implementation protocols that maintain control of viable GMOs, e.g., access to trial sites, restricted visibility and access from public throughways, *etc*.
c) Harvest protocols that minimize the distribution of viable GMOs, *e.g.* small machinery; cleaning machinery; packaging, labelling and documentation of viable material to be removed from the authorised site, *etc*.
d) Waste disposal that ensures de-vitalization of GMOs, *e.g*., ploughing or burying for plants, autoclaving for clinical trials.

5.3.6. Termination of confined trial

The critical aspects of termination of a confined trial are:

a) Maintaining security and control over the material in the field site

b) Preventing the release of planting material from the trial site

c) Appropriate measures for destruction of material in the trial site, or for storage and shipping of any material to be retained

d) 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:

a) Procedures employed or to be employed in terminating the trial;

b) Measures for de-vitalization and disposal of material from the trial;

c) Documentation and reporting requirements.

5.3.7. 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 include:

a) Maintaining control over the trial site and how it is used in post-harvest years

b) Ensuring that post-harvest use is compatible with the terms and conditions of the approval

c) Monitoring for volunteers and destroying these before they flower

d) 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 note of the following:

a) Post-harvest restrictions regarding ways in which the field may be used

b) Post-harvest monitoring and documentation requirements.

5.4. Introduction into the Environment (Commercial Release)

The critical aspects which the Inspectors would examine in a commercial release into the environment are as follows:

a. Maintaining reproductive isolation with neighbouring fields
b. Follow the required management practices e.g refuge cropping
c. Preventing the release of planting material from the site
d. Completing documentation requirements
e. Disposal or destruction of all residual material

The critical hazard points in a commercial release are identified during the risk assessment process and these are areas that inspectors will focus on when setting priorities for inspection and ensuring that adequate documentation is available.

5.5. Unintended Release

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

a) Containing the GMOs at the release site
b) Timely communication with regulatory authorities
c) Removing the GMOs from the site or rendering them non-viable
d) Preventing GMOs from being consumed by humans or animals
e) 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 regulatory authority, which will provide specific requirements for such inspection, according to the characteristics of the release.

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 authorised 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 authorised 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 authorised party that the regulatory authority will be in contact with them to establish what follow-up action will be required.

5.8. Inspection Report

The Inspector should complete 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 Biosafety Registry within 3 working days after the inspection.

This report may follow an established format, but should contain information on:

a) The date and purpose of the inspection

b) The activity's regulatory approval code

c) Details of what issues were identified

d) What follow up actions are recommended

e) Issues the regulatory authority is required to address with the authorised party

f) The name and signature of the inspector.

5.9. Responding to Non-compliance

When Inspectors discover non-compliance they can respond in several ways. The response is based on:

a) the regulatory requirements

b) the urgency of the situation

c) the level of risk to the environment

d) how readily corrective action can be implemented

e) the compliance history of the authorised party.

For the most part non-compliance is unintentional and can be quickly corrected. Most regulations allow the corrective action to be carried out by the authorised party who must 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, the regulatory authority 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. For example, some alternative mechanisms of reproduction isolation for field trials, such as flower removal or bagging, have an isolation distance as an approved alternative option if the first reproduction isolation mechanism fails. The authorised party can revert to the isolation distance if the other mechanism fails. Because this alters the terms and conditions for the trial and the post-harvest period, the regulatory authority needs to be notified to ensure that the inspectors are alerted to the change.

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 the regulatory authority and have them provide an acceptable corrective action and the approval to implement it. In other instances, where the risk to the environment and human health is real and imminent and the inspector cannot obtain timely approval for the corrective action, they may not be able to delay a decision to respond to the risk. Thus, it is important that the Biosafety Inspectors are able to evaluate risks to the environment under time constrained situations and that they have the authority to act, if this will prevent an unauthorised release or minimise the impact of the release.

6. Model Forms for Inspections

These model forms are examples that should be adapted to reflect the requirements of the Biosafety Regulations. They may need to be adapted to meet the needs of specific GMOs or specific GM activities and should be considered as working documents that are reviewed as and when needed. Appended to this document are forms for the following activities:

a) Facility inspection form
b) Shipping and storage inspection form
c) Confined trial inspection form
    i. Confined trial protocol inspection form
    ii. Confined trial termination inspection form
    iii. Confined trial post-harvest inspection form

d) Introduction into the environment (Commercial Release)

e) Unintended release & non-compliance inspection form

f) Record review and exit meeting inspection form

g) Inspection report

6.1 Facility Inspection Form

FACILITY INSPECTION FORM			
Facility address (location):			
Authorization Code Number(s), if any:	**Manager:**		
Inspector:	**Date of Inspection:**		
FACILITY			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
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 labelled and secured from unauthorised 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 of 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 Signature:	**Date:**
Site Manager Signature:	**Date:**

6.2 Shipping & Storage Inspection Form

SHIPPING & STORAGE INSPECTION FORM	
Storage Site Identification:	
Authorization Code Number(s):	**Site Manager:**
Inspector:	**Date of Inspection:**

PACKAGING AND LABELLING		
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Are the packaging layers sufficient for the material?		
Are different GMOs sufficiently separated in the package to prevent mixing?		
Is each layer of packaging labelled as required?		
If the packaging has not been retained, has authorization 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 Signature:	**Date:**	
Trial Manager Signature:	**Date:**	

6.3. Confined Trial / Commercial Release Inspection Form

CONFINED TRIAL/COMMERCIAL RELEASE INSPECTION FORM		
Trial Site Identification:		
Authorization Code Number(s):	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
TRIAL LAYOUT		
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Do site security measures meet the requirements?		
Was all GM material planted after the authorization date?		
Authorization Date: / Planting Date(s):		
Have all personnel with access to the site been trained in the confinement requirements?		
Are measures for cleaning equipment and access control sufficient to prevent loss of GM planting material?		
Has excess planting material been properly disposed of or retained in secure storage?		
Is the trial site and layout properly labelled? (*Response not required in commercial release)*		
Has a Record of Planting, including a final map of the site, been completed and submitted to the regulatory authority? Date sent:		
Does the size of the trial fall within the requirements for this activity? (*Response not required in commercial release)* Actual measurement:_____ m X _____ m = _____ square metres		
Comments:		
REPRODUCTIVE ISOLATION		
Is the spatial isolation distance free of prohibited plants?		
Has the spatial isolation distance been monitored and documented according to requirements?		
Were all prohibited plants in the spatial Isolation distance identified and destroyed before flowering?		
List other measures for reproductive isolation that have been implemented:		

Isolation Measure	**Procedure/Equipment Required**	**In Place? (Y/N)**

Have these additional reproductive isolation measures been monitored and the monitoring recorded?		
Comments:		
DATA COLLECTION (*Response not required in commercial release)*		
Has data been collected from the trial in accordance with the protocol?		
Comments:		
Inspector Signature:	**Date:**	
Trial Manager/Farmer Signature:	**Date:**	

6.3.1. Confined trial protocol inspection form

CONFINED TRIAL PROTOCOL INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL DESIGN AND INITIATION			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
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?			
Comments:			
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 regulatory authority?			
Comments:			

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

Inspector Signature:	**Date:**
Trial Manager Signature:	**Date:**

6.3.2. Confined trial termination inspection form

CONFINED TRIAL TERMINATION INSPECTION FORM			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TERMINATION OF THE TRIAL			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Was the regulatory authority 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 material?			
Are any GMOs to be retained?			
If yes, has the retention of GM material from the trial been by the regulatory authority?			
Do measures for packaging, labelling and transport meet the regulatory requirements?			
Is any non-viable GM material to be moved off-site for disposal?			
Comments:			
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 a trial termination report been completed and submitted to the regulatory authority? Date sent:			

Comments:	
Inspector Signature:	**Date:**
Trial Manager Signature:	**Date:**

6.3.3. Trial post-harvest inspection form

TRIAL POST-HARVEST INSPECTION FORM		
Trial Site Identification:		
Authorization Code Number(s):	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
POST-HARVEST RESTRICTIONS		
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
What crop will be or has been grown on the post-harvest site?		
Does this crop meet the regulatory requirements?		
Does the party 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?		
Comments:		
POST-HARVEST MONITORING		
Is post-harvest monitoring being carried out and documented according to requirements?		
Are volunteers being destroyed and disposed of according to requirements?		
List measures for destruction and disposal of volunteers:		
Are measures in place for cleaning equipment that is used to destroy volunteers?		
Comments:		

Inspector Signature:	**Date:**
Trial Manager Signature:	**Date:**

6.4. Trial Record Review and Exit Meeting Inspection Form

TRIAL RECORD REVIEW AND EXIT MEETING INSPECTION FORM	
Trial Site Identification:	
Authorization Code Number(s):	**Trial Manager:**
Inspector:	**Date of Inspection:**

TRIAL RECORDS AND FILES

Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Are copies of guidelines, SOPs, terms and conditions of authorization and other relevant documents readily available to trial personnel?		
Are trial records and files organized and stored in a secure 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:		

EXIT MEETING (ATTACH ADDITIONAL PAGES IF NEEDED)

Comments or concerns of Inspector:
Comments or concerns of Trial Manager:

Any follow-up actions recommended and responsibilities allocated:	
Comments:	
Inspector Signature:	**Date:**
Trial Manager Signature:	**Date:**

6.5. Customs and Border Inspection Form

CUSTOMS AND BORDER INSPECTION FORM					
Name of Importer					
Address					
Consignment					
Quantity					
Intended Use					
Vehicle Registration #					
Date					
Consignment Docs					
NAMBOARD Permit					
Export Permit					
Import Permit (SEA)					
Non-GM Certification					
Emergency name & Contact					
Transport Containment Measures					
Requirement for GM spot check					
Testing Results					
Requirement for lab testing					
Name of Inspector					
Comments or concerns of Inspector					

Transport Containment Measures:

- P – Poor
- S – Satisfactory
- G – Good

6.6. Unintended Release & Non-Compliance Inspection Form

UNINTENDED RELEASE & NON-COMPLIANCE INSPECTION FORM		
Trial Site Identification:		
Authorization Code Number(s):	**Trial Manager:**	
Inspector:	**Date of Inspection:**	
UNINTENDED RELEASE OR NON-COMPLIANCE		
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Was any unintended release recorded?		
Was any non-compliance incident recorded?		
Note: If no incidents occurred, skip the following questions and sign below.		
Briefly describe the incident:		
Where required, was the incident reported to the Regulatory Authority?		
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 Signature:	**Date:**
Trial Manager Signature:	**Date:**

6.7. Inspection Report

INSPECTION REPORT	
Trial Site Identification:	
Authorization Code 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 ACTIONS RECOMMENDED, RESPONSIBILITY, AND TARGET DATE			
Follow-Up Action	**Responsibility**	**Target Date**	**Re-Inspection?**

			(Y/N)
Comments:			
Inspector Signature:		**Date:**	
Date Submitted:			