BIOSAFETY GUIDELINES

CONFINED FIELD TRIAL OF LIVING MODIFIED PLANTS IN MALAYSIA

DEPARTMENT OF BIOSAFETY

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ISBN No: 978-967-10117-6-8

The Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010, Guidelines and Forms may be downloaded from the Malaysian Biosafety Clearing House Website at http://www.biosafety.nre.gov.my

Any future regulations, guidelines and related documents will be posted to this website.

ACKNOWLEDGEMENT

We wish to thank and acknowledge Dr. Vilasini Pillai, Prof. Dr. Yasmin Othman and Prof. Dr. Norzulaani Khalid for their effort and time in drafting this Guideline. Our thanks also go to all others who generously contributed to this Guideline.

CONTENTS

CHAPTER 1

INTRODUCTION TO THE GUIDELINES FOR CONFINED FIELD TRIALS OF LIVING MODIFIED PLANTS

1.1 INTRODUCTION

Researchers and technology providers of modern biotechnology are committed in producing products that will provide maximum benefit to society but at the same time pose no risk to human health and to the environment. From the research and development stage of a living modified organism (LMO) to its commercialisation stage and placing it on the market, rigorous regulatory compliance has to be ensured. Regulatory compliant practices are pertinent to maintain public confidence in the technology and in its products that have been placed in the market will not pose any risks to human, plant and animal health as well as to biological diversity.

The development of a LMO from containment will have to be progressively tested before its commercialisation (Figure 1). In the case of living modified plant (LM plant), the next stage after evaluation under contained facilities would be evaluation in confined field trials (CFTs). CFTs are controlled small-scale experimental field trial introduction of LM plants into the environment at a defined location for a limited time. The main objective of a CFT is to evaluate the LM plants with new genetic and phenotypic traits in the environment while ensuring that dissemination of the plants and the inserted gene is restricted. Field testing of LM plants will provide researchers with an opportunity to collect information, characterise, and evaluate the LM plants' potential agronomic benefits and observe their interactions with the environment. The information and data collected will be critical for a risk assessment required by the regulatory authority when submitting an application for approval for further unconfined field trials or commercialisation.

The first CFTs were carried out in the United States in 1987. Following that many CFTs have been conducted in various countries around the world. These trials have been conducted without harm to the

environment, to animals or to humans; this was accomplished by responsible management of CFTs by researchers and support from regulatory authorities. Thus, a combination of robust regulatory framework, science based risk mitigation measures, trained enforcement staff and field personnel are crucial to ensure effective confinement of the field trial.

CFTs not only are a prerequisite to the eventual unconfined environmental release of LM plants; plant breeders use CFTs to evaluate agronomic potential of novel plant-trait combinations. In addition, CFTs are also used to produce sufficient quantities of plant material for use in livestock feeding trials and to conduct compositional analysis for human food safety assessment. For plants that are amenable to vegetative propagation, CFTs also serve as a source of planting material multiplication. These trials also serve to provide data on the impact of the LM plants on non-target beneficial and endangered insects, and an assessment of morphological characteristics that could signal any changes to agronomic impact. CFTs can be multi-locational, representing a range of growing conditions and over multiple years. We have to take cognizance that most lines under CFTs do not end up as commercialised products (Figure 1).

The objective of this guideline is to provide researchers with the necessary practices when conducting a CFT of LM plants or crops to fulfil biosafety regulatory compliance. It also gives guidance on practices that will prevent pollen or seed dissemination into and within the environment, persistence of the LM plant or any of its parts and its progeny in the environment, and to prevent entry of the LM plant or plant products into the human food or animal feed chain.

Confinement of a field trial in this document refers to reproductive isolation but depending on the case, it may also require a physical barrier or isolation as prescribed by the regulatory authority to prevent destruction by animals or unauthorized removal of the LM material by humans.

Under the **Second Schedule of the Biosafety Act 2007**, approval is required from the National Biosafety Board (NBB) before CFTs are carried out. Specific forms are to be filled in and submitted to NBB with a specified fee according to the **Third Schedule of the Biosafety (Approval and Notification) Regulations 2010**.

1.2 TRAINING OF PERSONNEL

1.2.1 Transportation and Storage of Experimental Living Modified Plant Material

Training of personnel involved in shipment and/or receipt of experimental LM plant material, and those who may have access to

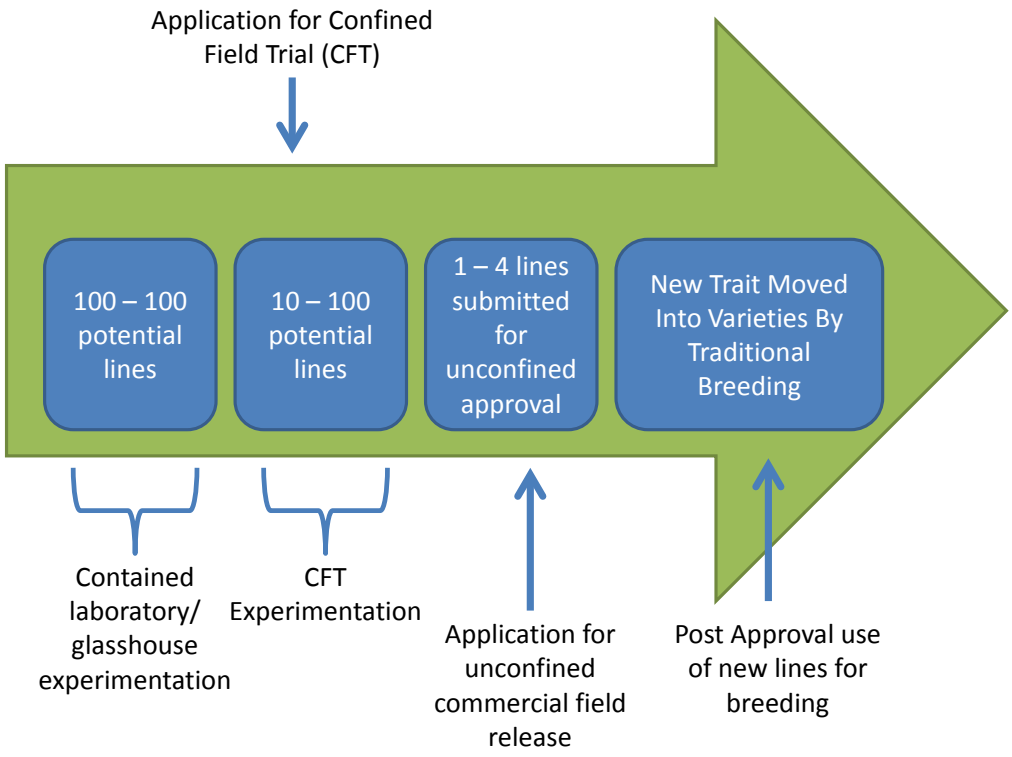

Figure 1. *From Lab to Market*

material storage areas must be done on regular basis. This is to ensure that they understand their responsibilities. Firstly, this material must be properly handled, packaged, labelled and stored. Secondly, appropriate records of these materials must be kept. Finally, personnel must know what actions should be taken and by whom in the event of an unintended release.

For management of the confined trial site, all personnel who have access or work on the trial site during the pre-planting, planting, growth, sampling, on-trial harvest, final harvest and the post-harvest period (current season) should understand their responsibilities for ensuring that the trial remains confined, appropriate records are kept, and what actions should be taken and by whom in the event of damage to the trial site or an unintended release. The training should be relevant to the activities that each staff member may undertake. For example, training related for in-field monitoring may be different from weeding during the trial. Copies of relevant standard operating procedures (SOPs) should be accessible to all personnel.

1.3 REGULATIONS PERTAINING TO CONFINED FIELD TRIALS

The terms and conditions governing the conduct of CFTs include specific provisions for reproductive isolation, physical security as necessary during transportation, planting, monitoring, sampling, on-trial harvesting, final harvesting, storage, disposal, unintended release and reporting will be stipulated in the certificate of approval by the NBB **[Part III, Approval for Release and Import, Biosafety Act 2007, Parts III and IV, Biosafety (Approval and Notification) Regulations 2010]**.

1.3.1 Risk Mitigation Measures for CFTs

The risk mitigation measures to ensure the safe conduct of CFTs takes into account pollen- or seed-mediated dissemination of new genes into and within the environment; persistence of LM plant and its progeny in the environment and introduction of the LM plant or its products into the human food or livestock feed pathways. These measures help to ensure that the CFTs do not negatively impact the environment, animals, humans and the country's biodiversity.

1.3.2 Preventing the Dissemination of New Genes

Preventing the dissemination of new genes through reproductive isolation refers to the means used to control the movement of pollen from the CFT into neighbouring plants of the same or a sexually compatible species. This includes other cultivated plantings or free-living plants of the same crop species, and any compatible wild plants of a species related to the crop. Pollen-mediated gene flow and introgression occur, only when the two plants are sexually compatible, fecundity must coincide, a pollen vector must be available, and the progeny plants must be fertile and able to persist in the environment.

In order to ensure reproductive isolation, crop specific protocols must be followed by removal of flowers, bagging of flowers/tassels to prevent open pollination; termination of the trial prior to flowering; spatial and/or physical isolation from other sexually compatible plants; use of border rows of conventional plants of the same variety to act as pollen traps for insect-pollinated species; and temporal isolation of pollination (*i.e.*, planting earlier or later than any nearby sexually compatible plants).

Spatial isolation is the basic method of reproductive isolation for all plant species based on appropriate distances already documented.

For risk assessment of a CFT, one of the most important considerations is whether the method of genetic improvement, or the trait introduced into the LM plant, is likely to alter the basic reproductive biology of the unmodified plant species. It is important that all neighbouring farmers

be informed of the planned trials especially if the reproductive isolation may have an impact on farm management of fields adjacent to the trials.

1.3.3 Preventing Persistence in the Environment

It is crucial that LM plants, or its progeny, will not persist in the environment at the end of the CFT. Any viable progeny plant materials (volunteers) in subsequent growing seasons should be managed to prevent persistence in the environment. There should be a period where planting of the same or a sexually compatible plant species is prevented and active monitoring is to be carried out. Any volunteer or prohibited plants must be destroyed before flowering.

The period of post-harvest restriction depends on the plant species and particularly its seed dormancy characteristics. It is important to consider whether the genetic improvement is likely to have altered any properties of seed dormancy. If it has not, then knowledge of the persistence of viable seed from the conventional variety in the soil can be used to determine the appropriate period of post-harvest restriction and monitoring.

1.3.4 Preventing Introduction into the Food and Feed Pathways

A major critical control point in the proper management of CFTs is the prevention of introduction of LM plant material into food or feed pathways. Environments where experimental plant material is routinely harvested for local consumption at the end of conventional trials represents the most likely scenario in which an unintended release of regulated material may happen during a CFT. Effective risk management to prevent animal or human consumption of regulated plant material requires: Controlling the movement of plant material to and from the trial site; Controlling the storage of seed and other plant material; Controlling the disposal of residual or excess plant material on the trial site; Controlling the disposal of any material retained after harvest, such as seed that is saved for subsequent analyses; and controlling unlawful harvest from the trial site.

Implementation of effective and documented control processes, and a system of traceability, all of which are backed up by inspection and verification procedures must be established.

1.4 GENERAL REQUIREMENTS

One of the most important areas to be considered in an application for a CFT is the ability of the Principal Investigator (PI) to satisfactorily implement an appropriate compliance management programme. In this regard, the PI's prior training and experience, coupled with the PI's own

history of successful compliance management, are significant factors that may influence the granting of an approval for a CFT application.

All field experiments of LMO are considered a release activity and therefore must obtain an approval from NBB [procedures are outlined in **Biosafety (Approval and Notification) Regulations 2010**]. The application for field experiment should be vetted by the Institutional Biosafety Committee (IBC) before submission to the NBB. The IBC assessments should be attached to the top sheet of the corresponding application form and submitted to the NBB. The PI must obtain an endorsement from IBC and should not start a field experiment until a certificate of approval is granted by the NBB. Measures for the control and confinement of field work must comply with conditions imposed by NBB.

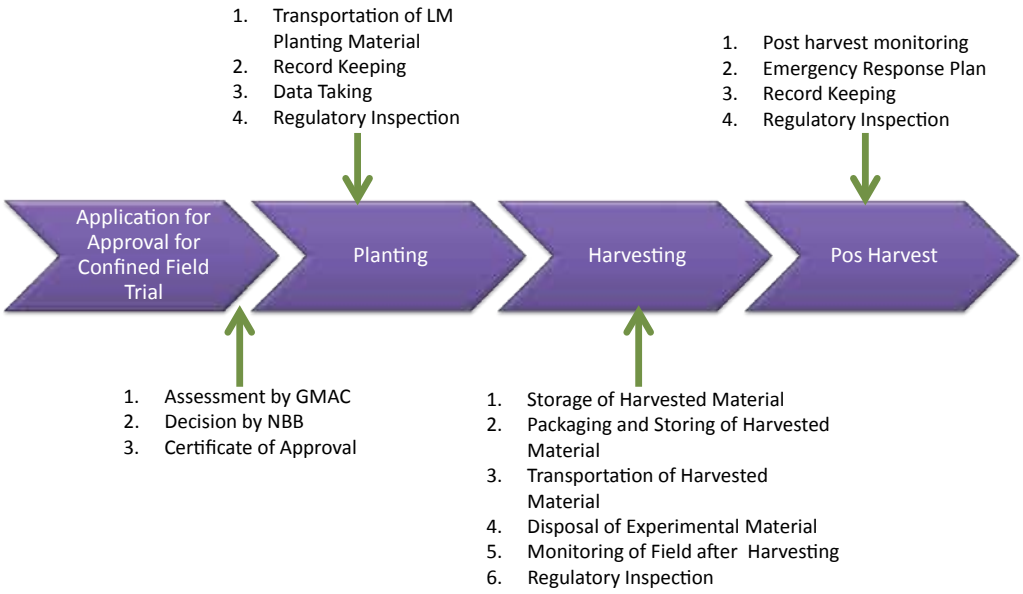

***Figure 2**. Confined Field Trial Process*

1.5 CONCLUSION

The focus of a CFT must be on the implementation of effective risk management strategies as the ultimate goal of the CFT is to prevent unintended release of the LM plant material into the environment while undertaking the field trial to collect relevant data for subsequent confined and unconfined release experiments or for commercialization.

One of the goals of this document is to provide some guidance and information to researchers before they embark on a CFT of LM plants. In a CFT, researchers are able to safely evaluate LM plants with new genetic traits in their natural environment by following basic principles of confinement and biosafety. The regulation, conduct, and oversight of CFTs requires a comprehensive and integrated approach spanning all aspects of the trial, from the inception of planning to successful completion and reporting of the trial and results.

CHAPTER 2

APPLICATION FORM FOR CONFINED FIELD TRIALS

2.1 INTRODUCTION

The NBB has introduced a standard form (NBB/A/ER/10/FORM A) for an applicant to seek approval for CFTs. The application form contains sufficiently detailed instructions to allow the applicant to complete the form correctly and expeditiously.

2.2 SUBMISSION OF THE APPLICATION

Submission of the application shall be channelled through the respective IBCs, whose role is to ensure completeness of the application form and verify availability of the proposed facilities before endorsing and forwarding the application to the Director General (DG) of the Department of Biosafety in the prescribed manner, together with the prescribed fees and be accompanied with:

- risk assessment and a risk management report
- emergency responses plan
- other information as may be specified by the NBB.

Applications for a CFT must be received at least 180 working days in advance of the proposed trial start date. The DG shall review the application for completeness and initiate the official review process if the application is found to be complete. Applications that are incomplete or deficient are returned to the applicant with a listing of information required to address any deficiencies. Refer to Appendix 1 for the application form (NBB/A/ER/10/FORM A).

2.3 REVIEW AND AUTHORISATION

Upon receiving the application, the DG in his/her capacity as the secretary of NBB, shall

- Refer it to the Genetic Modification Advisory Committee (GMAC) for its recommendations,

- Refer it to relevant government agencies for specific matters
- Invite public participation for purpose of public disclosure

GMAC shall do a science-based assessment and forward its recommendation whether or not the application should be approved and the terms and conditions to be imposed by the NBB, if any, after the assessment. After having considered the recommendations of the GMAC, the comments of the relevant department or agency, the views of members of the public, if any, and any additional information, the NBB may grant the application by issuing a certificate of approval or refuse the application.

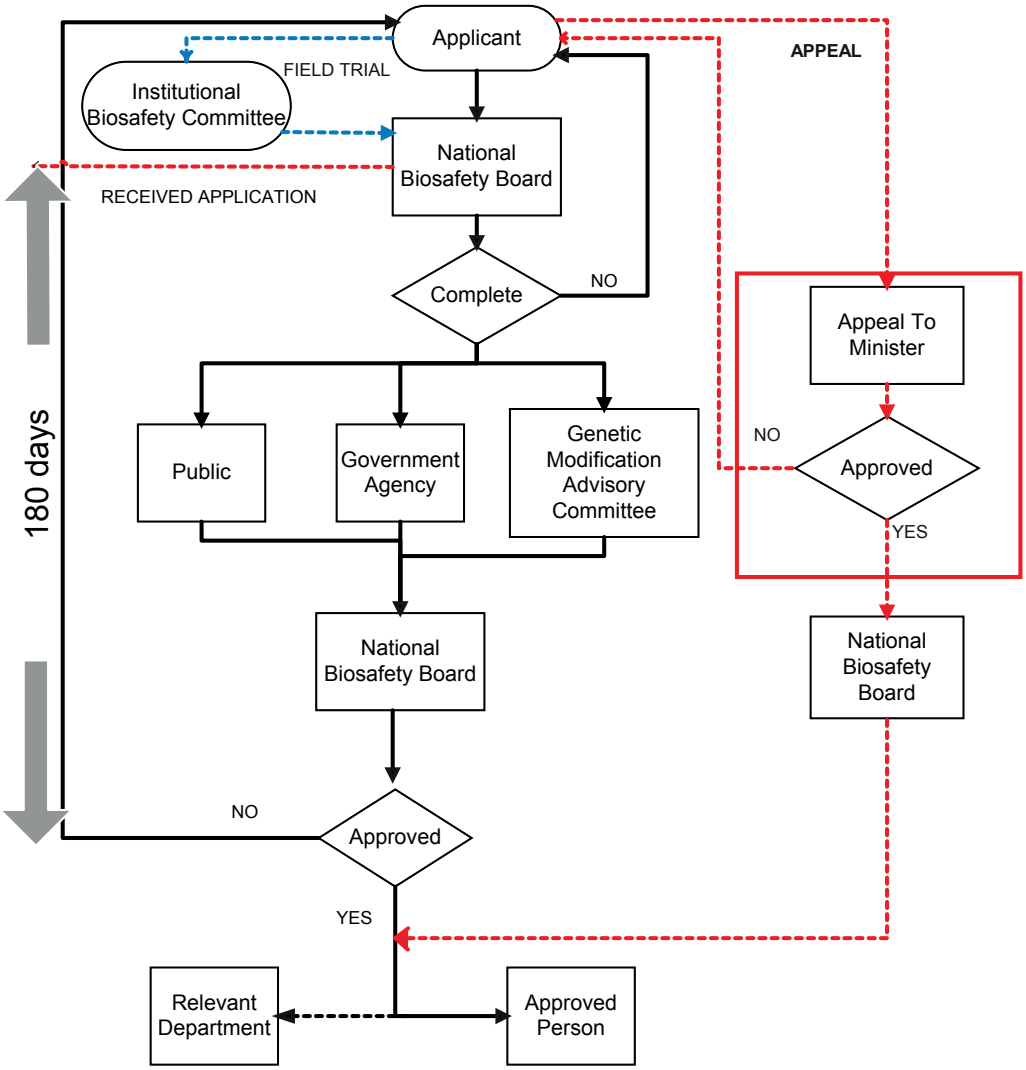

***Figure 3**. Approval Process*

CHAPTER 3

TRANSPORTATION AND STORAGE OF EXPERIMENTAL LIVING MODIFIED PLANTS

3.1 INTRODUCTION

Confinement starts not only at the trial site but already during transportation and storage of LM plant material, specific confinement measures should be adopted. This chapter provides guidance on appropriate measures on the transport and storage of experimental LM plants and plant material for CFTs to ensure that there is no unintended release. Guidelines on preventive measures during transportation and storage have also been provided in the ***Biosafety Guidelines for Contained Use Activity of Living Modified Organism (LMO)***.

3.2 TRAINING OF PERSONNEL

All personnel involved in the transport and storage of LM plant material should be properly trained so that personnel understand their responsibilities to ensure that the LM material is properly handled, packaged, labelled, stored and the appropriate actions that need to be taken in the case of an unintended release. It is also important that proper records are kept and they should be made available to all personnel involved in the CFTs.

3.3 IMPORT OF EXPERIMENTAL LIVING MODIFIED PLANT MATERIAL

Appropriate permits should be obtained before importing experimental LM plant material into the country. **Part III of the Biosafety Act 2007, section 13(1)** clearly indicates that an approval is needed for the importation of LM plant material. Both the country of import and export must be aware of and comply with the obligations under each of the country's Biosafety regulatory regime or the Cartagena Protocol on Biosafety if they are parties to it.

3.4 PACKAGING AND LABELLING

All material intended for CFTs must be packaged and labelled to prevent

unintended release. Multiple layers of packaging may be required according to the material being transported. The inner container, usually in direct contact with the LM plant material, is called the 'primary container', and is enclosed within 'secondary' and perhaps 'tertiary' containers. Each layer of packaging must be such that it prevents the release of the LM plant material under normal conditions, and each layer must be independently closable or sealable. An example of a shipment label is given below (Figure 3.1).

LIVING MODIFIED PLANT MATERIAL FOR RESEARCH PURPOSES ONLY. DO NOT USE FOR FOOD OR FEED.		
Shipment No:	Item No:	Unique Identifier or Event Name:
Certificate of Approval No:		Plant Species:
Form of LM Plant Material: Seed ☐ Budwood/Shoots ☐ Transplants ☐ Tuber ☐ Whole Plants ☐		
Identify any Seed Treatment or Other Treatment of the Material:		
Emergency Contact Person:		Telephone:

Figure 3.1. *Sample of a Shipment Label*

3.4.1 Seeds, Propagules or Plant Parts

These materials should be transported in a durable bag or a sealed envelope or package constructed out of tear and moisture resistant material as primary container. The primary container can contain only plant material of a single type derived from on line or single event. It should not be mixed up with non-modified planting material. The primary material should be placed within a sealed, leak-proof secondary container which is resistant to breakage or water damage. Examples of appropriate primary containers for seeds are: metal cans, plastic bottles, plastic bags. Fibre bags may be appropriate if the mesh size and construction are adequate for the type of seeds being contained. Appropriate secondary containers include: plastic or metal cans or boxes, cardboard or fibreboard boxes or wooden boxes of close-fitted construction. Seeds of different lines or events may be separated in sub-containers within the primary container.

3.4.2 Seedlings and Plants

Seedlings and plants should be transported in non-breakable container as primary container. The primary container should be placed within a leak proof secondary container, which is resistant to breakage or water damage. Sufficient packaging material should be included around the primary container to prevent movement and damage during transport. LM plants that are two metres or more in height and have not started flowering will need to be transported in a fully covered vehicle which has a floor layered with a durable plastic. No plants bearing flowers or buds should be transported. The vehicle compartment containing the LM plant material should be sprayed with pesticide before and after transportation.

Every layer of the required packaging must be labelled with sufficient information to establish the identity of the contents, and the contact details of an official contact person. The label should also be labelled indicating '**Living Modified Plant Material for Research Purposes Only. Do Not Use for Food or Feed**'. Primary containers shall be labelled with a user identification number (*e.g.*, event name or number or other unique identifier), the type of LM plant material contained within. All secondary containers used to transport LM plant material shall be labelled with a Transport Label securely affixed to the outside, indicating the name of the person to be contacted in a case of an emergency.

3.5 DISPOSAL OF EXPERIMENTAL LIVING MODIFIED PLANT MATERIAL

Primary and secondary containers used to transport LM plant material shall be sanitized prior to filling and after the plant material has been removed, if intended to be re-used. Alternatively, if the containers are not for re-use, they may be destroyed by incineration.

The process of cleaning will vary with the type of container and the material being contained. Outer layers of packaging that are not in contact with LM plant material may be returned to general use without restriction, unless a breach of the primary container has occurred, in which case packaging that has come in contact with LM plant material. Alternatively, containers may be destroyed after use by burning or treatment with appropriately labelled herbicides and/or chemicals. Any residual plant material recovered during the process of cleaning should be rendered non-viable. The acceptable means for rendering experimental plant material nonviable and for its subsequent disposition must be approved by the NBB.

3.6 RECORDS

It is important to maintain adequate records of the transport of experimental LM plant materials as they move between research

facilities, storage facilities and field trial sites. Such records may be examined by IBC, DG or his authorised inspectorates to ensure that there is an adequate system in place for tracking the movement of experimental LM plants.

3.7 STORAGE OF EXPERIMENTAL LIVING MODIFIED PLANTS

All LM plant material must be stored and maintained in such a fashion as to preserve its identity, security and integrity, and to prevent it from being consumed by humans, livestock or other animals Generally, a suitable storage area is a fully enclosed one where the plant material can be stored separately from other experimental or conventional plant materials like a filing cabinet, office, cold room etc. with access doors that can be locked. All windows if present should be kept closed and locked as well. Access is restricted to authorized personnel only. The facility or storage area is sign-posted with the information 'LM Plant Material – Not for Use in Food or Feed'. Storage areas should be cleaned prior to and following the storage of LM plant material. All LM plant material must be kept separated from non- LM plant material if they are stored or maintained in the same facility or area. LM plant material must be clearly marked or labelled. An inventory of all LM plant material being stored or maintained in a storage area must be kept in order. Where a single storage area is used to store multiple samples of one or more modern biotech-derived events, each line, variety or event should be stored separately in a sealed, labelled container. An example of an identification label for the point of entry to a storage area is given below (Figure 3.2).

THIS STORAGE AREA CONTAINS EXPERIMENTAL LIVING MODIFIED PLANT MATERIAL	
IN CASE OF EMERGENCY OR DAMAGE TO THE STORAGE AREA, CONTACT THE BIOSAFETY OFFICER/FACILITY MANAGER IMMEDIATELY	
Facility Name or Code:	
Building Name or ID:	
Room Number or Description:	
Name of Facility Manager:	Telephone Number:
Name of Biosafety Officer:	Telephone Number:
ACCESS TO THIS STORAGE AREA IS LIMITED TO AUTHORISED PERSONNEL ONLY	

Figure 3.2. *Sample of Identification Label for the Point of Entry to a Storage Area*

3.8 EMERGENCY RESPONSE PLAN

In the event of an unintended release into the environment of experimental LM plant material during transport or storage, the incident should be stabilised and effort should be made to recover as much of the experimental material as possible. If a third-party is involved in transport or storage, the PI should be notified immediately of the situation. The location of an unintended release should be marked and managed to ensure that no additional release of material occurs. Any corrective actions taken to address an unintended release during transport or storage should be documented. The DG and the IBC should be notified when an unintended release has occurred. Additional management practices or additional training of personnel to ensure that the situation is not repeated should also be considered. The PI's IBC should be notified within 24 hours, and the NBB should be notified within 48 hours of the unintended release (refer to incident reporting form, IBC/IR/10/ANNEX3).

MANAGEMENT OF CONFINED FIELD TRIALS

CHAPTER 4

4.1 INTRODUCTION

CFTs are the next step after initial screening of LM plants in contained facilities. In CFTs of LM plants, researchers have an opportunity to evaluate the agronomic performance and the environmental suitability of these modified plants, as well as to collect data required for safety assessment and variety testing. These CFTs are also used to select lines for further testing as well as to eliminate lines that do not exhibit the desired characteristics. These initial field trials are also important to provide data to regulators for them to make informed decisions for approval in cases of further testing or unconfined releases. These CFTs should be managed according to practices designed to confine the trial during the growing as well as post-harvest period to prevent unintended releases into the environment to ensure there are no adverse effects on the environment, to human and animal health. Typically this will include reproductive isolation of the LM plants in the field trial, restrictions on accessibility to the trial sites as well as restrictions on the use of the sites after harvest.

This chapter outlines practices that can be followed to ensure the safe management of CFTs of LM plants during the entire growing period as well as after harvest.

4.2 TRAINING OF PERSONNEL

The PI has to ensure that all personnel involved in the field trial of LM plants during the entire growing period, including onsite weed and pest management, as well as after harvest are trained to handle the specific LM plant. These personnel must be made aware of their responsibilities, restrictions to the field trial sites, proper record keeping, maintaining the confinement of the field trial sites, measures that should be taken if there is breach in any of the set protocols and the authority that should be notified if there is any damage or unintended release. SOPs should also be made available to the personnel involved in the field trial.

4.3 PLANTING OF CONFINED FIELD TRIALS

4.3.1 Selection of Trial Site

There are various factors that should be kept in mind when selecting a site for the proposed confined field trial of LM plants. The surrounding ecosystem should be taken into consideration when choosing the site to ensure environmental safety issues are addressed. The size of the field trial should be manageable to allow continual monitoring. Please note the following information is required when filling in the application form (NBB/A/ER/10/FORM A):

1. Site map(s) with national grid reference(s);
2. Details of the reasons for the choice of the CFT site(s);
3. The preparation of the CFT site(s) before the CFT (s);
4. The methods to be used for the CFT (s);
5. The quantity of the LMO to be planted in the CFT ;
6. The physical or biological proximity of the CFT site(s) to humans and other significant biota or protected areas;
7. The size of local human population;
8. The local economic activities which are based on the natural resources of the area;
9. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes;
10. The flora and fauna, including crops, livestock and migratory species in the CFT site(s);
11. The comparison of the natural habitat of the parent organism(s) with the proposed CFT site(s); and
12. Any known planned developments or changes in land use in the region which could influence the environmental impact of the CFT.

4.3.2 Maps

Maps are important to facilitate monitoring of the trial site during the growing season and post harvest period. They also provide the DG or his/her authorised enforcement officers with the exact location of the trial site for inspection purposes. Maps must be submitted to the NBB when applying for approval for CFT. The maps must have sufficient details to allow the authorised enforcement officers to locate the field trial site during the growing as well as during the period of post-harvest

land use restriction. All maps must be legible and precise. Maps prepared in advance of planting should be reviewed at planting to ensure that the information on the preliminary map remains accurate.

The maps must include the following information:

- The general location of the field trial (city/town/region), and sufficient information to locate the trial site from the nearest town. The latter may be a map of the local area, indication of a specific milepost or landmark on a major road, or written directions to the trial site;
- Compass directions with North at the top of the page;
- Location of the trial site in relation to permanent landmarks such as roads, buildings or fences;
- Global Positioning System (GPS) coordinates of the site may be provided;
- Exact dimensions of the trial site must be indicated on the map;
- Total area planted with the experimental LM plant, including guard rows (square meters or hectares) must be indicated;
- Closest fields of the same species as the experimental LM plant up to one km from the trial site where reasonable;
- Any natural ecosystems adjacent to the trial site (natural habitats, waterways, forests, conservation areas or other protected habitats) must be indicated on the map;
- If the area of a previous trial is still under post-harvest land use restriction at the same site, the restricted area should be indicated; and
- The name and telephone number of the field trial manager or field contact must be provided.

An example of a sample trial site map is given below (Figure 4.1).

4.3.3 Identification of Confined Field Trial Site

A CFT site should be identified with a sign board indicating the **IBC Project Identification number** as well as the **NBB Certificate of Approval number**. It should also indicate the name of the specific LM plant on trial and have the following clearly indicated on the board "***LM Plants- for experimental purposes only and not for human or animal consumption***.- ***Authorised Personnel Only***" or similar phrases.

4.3.4 Cleaning of Field Equipment

All equipment used for planting of LM plants or seeds must be cleaned prior to them being brought on to the trial site. Likewise all equipment

used on the trial site must be cleaned on site prior to removal to avoid unintended transportation or release of experimental material. Personnel working on the site and or visiting the site must ensure that their clothing and footwear is free of any plant material, seeds or pollen prior to leaving the site. CFT personnel should ensure that whatever

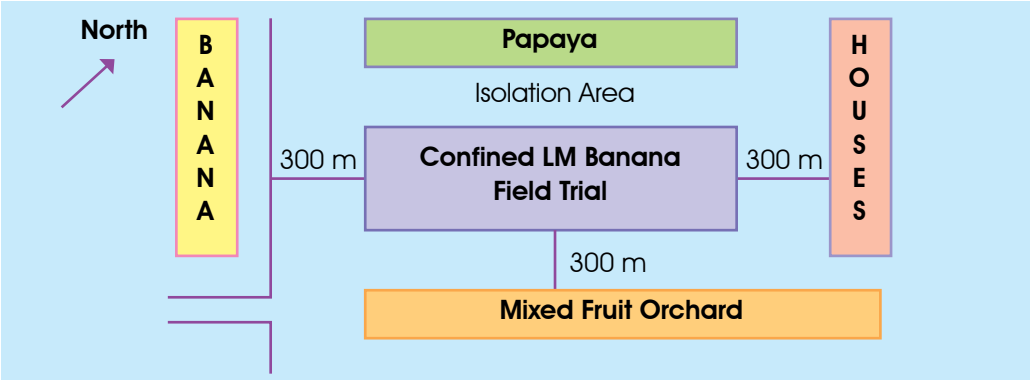

Figure 4.1. *Sample Trial Site Map*

planting material recovered from these inspections are disposed off according to procedures described in the "***Biosafety Guidelines for Contained use Activity of Living Modified Organism (LMO)***" or any suitable methods that will render the planting material nonviable. As far as possible, the material to be disposed should be made non-viable (please state examples of the methods employed to make the plant material non-viable) on trial site before removing it to ensure unintended release into the environment.

4.3.5 Isolation of Confined Field Trials

In order to maintain reproductive isolation of CFTs, it is important to be familiar with the reproductive biology of the LM plant species used in the CFT. This information can be obtained from breeders or biology consensus documents. NBB may also provide other acceptable methods to maintain isolation distances as part of their terms and conditions under the certificate of approval issued to the applicant.

4.3.6 Methods of Reproductive Isolations of Confined Field Trials

Each CFT should have a stipulated method of reproductive isolation and it will be crop specific. The following are some of the ways to maintain reproductive isolation and careful consideration should be given when choosing one.

I. Spatial Isolation

Field trials of LM plants must be isolated from other plants of the same

species or other relatives that are sexually compatible with them by a minimum isolation distance. There must be no other plants of the same species or sexually compatible relatives within the stipulated isolation distance. All plants found within this distance must be destroyed or made non-viable before anthesis or seed-set.

II. Temporal Isolation

Reproductive isolation can also be achieved by ensuring that planting of the LM plant is staggered to ensure that pollen shedding is complete before any other pollen is shed by plants of the same species or are sexually compatible with the LM plant that may be cultivated within the reproductive isolation distance. This method of reproductive isolation must be used with caution as accurate prediction of time of anthesis may be difficult due to inherent growing variability. Close monitoring must be carried out to ensure that anthesis of LM plants is non concurrent with that of other relatives or plants of the same species within the isolation distance.

III. Bagging of flowers

Field trials of certain plants can be isolated from same or related species grown in the isolation site by bagging the flowers or inflorescences to ensure that there is no pollen release before anthesis and they have to remain bagged until no more pollen shedding occurs. Where this method is used as a means of reproductive isolation, then the applicant must submit justification and detailed methodology to support the proposal.

IV. Removal of Flowers

Another method that can be used to isolate the LM plants from their sexually compatible relatives found in the isolation site is by removal of flowers from the experimental flowers before anthesis. As with temporal isolation, rigorous monitoring should be carried out to ensure that all the flowers are removed before anthesis.

V. Border Rows

Establishment of border rows or guard rows can be used to reproductively isolate the LM plants on trial from the same or related species. It is also useful if the plants are insect resistant as then the border or guard rows can attract the insects and reduce the flow of pollen via insects. In order for this method to be effective, the plants planted as border or guard rows must flower at the same time as the LM plants and be of the same growth habit and height. The width of the border row is species-specific and should be a continuous row without any break in the perimeter. It should also be planted at the same density as the LM plants and managed using standard agronomic practices.

The best species to use as the border row would be the same or similar genotype of the non-modified LM plant planted at the same time as the LM plant. Close monitoring must be carried out to ensure that the border plants do not flower earlier but flower concurrently as the experimental plants as well as to replace any of the plants that are inadequate. The size of the trial site must include the border rows.

The use of border rows can pose a challenge when heavy equipment is used as it may restrict the movement of such machinery. Care must also be taken when herbicide resistant LM plants are on trial to ensure that the herbicide susceptible border plants are not affected.

VI. Early Destruction of Living Modified Plants

Reproductive isolation of the LM plants with plants of the same species or same family can also be achieved by destroying the LM plants before anthesis.

4.3.7 Breach of Reproductive Isolation

Breach of reproductive isolation is a serious incident and must be reported to the PI's IBC and to the NBB. The PI may be requested to destroy the field trial or any plants within the spatial isolation distance.

Please note the following information which is extracted from Part B Risk Management of the application form (NBB/A/ER/10/FORM A) is required if breach of reproductive isolation happens:

I. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

II. Details of the proposed CFT site(s) supervision procedures and if necessary any relevant safety procedures designed to protect personnel, including a description of procedures for onsite supervision of the CFT if the trial site(s) is located at some distance from the location of the applicant.

4.4 EMERGENCY RESPONSE PLAN

There must be a clear emergency response plan in the case of an unintended release of the experimental LM plant into the environment. In the event that an unintended release into the environment of LM plant material during a CFT occurs, the following should be adhered to:

- the incident must be stabilised and prevention of further release ensured;
- prevention of consumption of LM plant material;
- recovery of released LM plant material;

- marking and recording the exact site of the incident;
- disposal of LM plant material, if required;
- follow-up monitoring and detection;
- Any corrective actions taken to address an unintended release during the CFT should be documented. The PI's IBC should be notified within 24 hours, and the NBB should be notified within 48 hours of the unintended release (refer to incident reporting form from the Guidelines for Institutional Biosafety Committee (IBC), IBC/IR/10/ANNEX3); and
- In case the unintended release has resulted in injury, the PI should notify the Occupational Safety and Health Committee (OHSC), IBC and NBB within 24 hours of the incident (refer to occupational disease/ exposure investigation form from the Guidelines for Institutional Biosafety Committee (IBC), IBC/OD/10/ANNEX4).

Please note the following information which is extracted from Part C Emergency Response Plan of the application form (NBB/A/ER/10/FORM A) is required:

i. Methods and procedures for controlling/removing the LM plants in case of unintended release or any adverse effects being realized

ii. Methods for isolation of the area affected

iii. Methods for disposal of other plants, animals and any other material exposed to the adverse effects

4.5 REPORTS AND RECORDS OF INCIDENTS

It is recommended that regular reports on the CFT be prepared for the NBB.

Reports that could be provided include:

- planting report, with details of trial establishment
- trial progress report(s)
- harvest report
- incident and corrective action report, if appropriate
- unanticipated effects report, stating details of such events
- experimental report, stating all observation and evaluation methods and outcomes of the trial

- post-harvest report, after the completion of the post-harvest period

The Department of Biosafety or their authorised enforcement officers could also regularly inspect the CFT site to ensure that all relevant measures and procedures for confinement are in place and implemented. In addition to the reports, it is recommended that records regarding transportation and storage of LM plant material, confinement measures at the trial site, disposal of LM plant material, reproductive isolation measures, planting and harvest procedures, general monitoring, post-harvest monitoring and any unintended releases and the corrective actions taken, be prepared and kept.

Records should include relevant information such as date and name of person doing the recording and be easily traceable and available for review and inspection.

Regular monitoring of CFT should be undertaken to ensure that the trial remains confined during the growing period. This will also provide for early detection of any problems with regards to reproductive isolation and will allow the trial personnel to carry out quick corrective action to address potentially non-compliance situations. Monitoring should also be done during collection of data as this is important for researchers wanting to move a LM plant forward for unconfined field trials or commercialisation as monitoring impacts on non-target organism, pest and disease susceptibility or altered behaviour (*e.g.* enhanced dormancy) is important to support an environmental risk assessment. Any technical or administrative compliance issues encountered during the growing season should be reviewed annually by the IBC to ensure continuous improvement of in-house compliance management programme.

CHAPTER 5

SAMPLING, RECORD KEEPING AND DISPOSAL

5.1 INTRODUCTION

The following guidelines and procedures for sampling, record keeping and disposal of material during an approved CFT is effective for any release activity, or any importation of LM plant material for release upon issuance of a certificate of approval. . Specific SOPs for different LM plant should be developed based on these guidelines and approved by the respective IBCs and the NBB before the trials can commence. Compliance to **Part IV Section 9(2) of the Biosafety (Approval and Notification) Regulation 2010** and information required in the application form **(NBB/A/ER/10/FORM A)** is referred.

5.2 SAMPLING OR HARVESTING FOR ANALYSES

The PI or Field trial Manager may have a need to sample and keep the LM plant material from the trial site as seeds or cuttings for future trials or as plant tissues as required for subsequent laboratory analyses. Sampling and harvest plans for each trial must be outlined in detail and provided during the application to NBB. No plant material from the trial can be allowed to enter the human food or animal feed chains.

5.3 STORAGE OF MATERIAL AFTER SAMPLING OR HARVESTING

All storage of material has to be carried out such that there is no release into the environment. The following provides the key considerations to be followed.

5.3.1 Storage Procedures

i. Proper segregation has to be provided for the sampled or harvested LM plant material prior to transportation, testing or storage.

ii. To ensure security, the storage facility should be a fully enclosed space (*e.g.*, filing cabinet, office, closet, cold room) with access doors

that can be locked. If there are windows, they should be kept closed and locked as well.

iii. Where a single storage area is used to store multiple samples of one or more events, each line, variety or event should be stored separately in a sealed, labelled container. This could be the primary container used for shipment as described in Section 5.4.1.1.

iv. Storage areas are to be clearly labelled as containing experimental LM plant material. Labels should be posted at the point of access, and access to the storage facility should be limited to authorised personnel only. An example of a storage area label is provided in Figure 3.2.

v. Storage areas should be cleaned prior to, and immediately following, the period of storage. Any residual plant material recovered during cleaning should be rendered non-viable and disposed off by a suitable method as approved by the NBB (see Section 5.6).

5.3.2 Inspection of the Storage Area

i. Inspection of the storage areas shall be carried out at specified intervals (as submitted in the application form) by the Facility Manager to ensure that storage conditions are maintained in accordance with section 5.3.1 in this Guideline. Each inspection shall be recorded in a Record of Storage Inspection and Inventory.

ii. The Record of Storage Inspection and Inventory shall be retained by the Facility Manager.

5.3.3 Corrective Action In The Event Of An Unintended Release

i. If an unintended release of LM plant material is suspected during storage, the Facility Manager shall treat this as a case of unintended release and immediately notify the PI who will initiate the emergency response plan (see Section 6.5) and take the appropriate reporting and corrective action.

ii. In the event of a confirmed unintended release of LM plant material, all attempts shall be made to recover as much of the LM plant material as possible. The recovered plant material shall be rendered unviable and destroyed (see Section 5.6).

iii. The location of an unintended release shall be marked and monitored to ensure that all the LM plant material arising from the unintended release (*e.g*. volunteer plants) is destroyed.

iv. The period of monitoring will be determined in consultation with the IBC and with approval of the NBB.

v. In the event of a confirmed unintended release during storage, the Facility Manager, through the PI shall notify the IBC within 24 hours, and the NBB within 48 hours of any unintended release during storage (refer IBC/IR/10/ANNEX3).

vi. The unintended release of LM plant material during storage shall be immediately documented by the Facility Manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Facility Manager and copies shall be submitted by email (attachments)/ facsimile to the PI and IBC.

v. All records associated with the storage of LM plant material shall be available for inspection by Department of Biosafety or its authorised enforcement officers upon request.

5.4 TRANSPORT OF LIVING MODIFIED PLANT MATERIAL SAMPLED OR HARVESTED FROM AN ON GOING TRIAL

For CFTs there is a need to pay attention to the manner in which, experimental LM plant material is both transported and stored during transportation. This section provides guidance on appropriate practices for the development of SOPs for the secure transport and storage of LM plants and plant material during transportation. Prior to sending the material, the Field Trial Manager must inform the recipient of the dispatch of the material. A **Transport Record** containing details of the materials being transported and the dispatch date and time of transport must be kept by the Field Trial Manager.

5.4.1 Storage During Transportation

5.4.1.1 Primary containers

i. All LM seed or propagable plant material must be stored in secure containers /packets for transportation and must be kept separate (secured in a primary container) from other plant material during transport.

ii. The Field Trial Manager will ensure that appropriate containers/ packaging materials are supplied to all agents working on their behalf for the purpose of transporting LM seed or propagable plant material. All LM plant material must be clearly labelled.

iii. Each sealed, primary container can contain only the approved LM seed or propagable plant material derived from one event. The primary container must be a sealable bag; envelope or package constructed of tear and moisture resistant material (*e.g.*, polythene bags, seed envelope, and cardboard box) and must be placed

within a sealable, leak-proof secondary container. Multiple primary containers can be placed within a single secondary container.

5.4.1.2 Secondary Containers

The secondary container must be resistant to breakage or water damage and should be constructed of materials such as corrugated fibreboard, corrugated cardboard, wood, or other material of equivalent strength.

5.4.1.3 Reuse of Containers

Primary and secondary containers used to transport LM seed or propagable plant material which is proposed to be reused must be cleaned after use. Alternatively, primary and secondary containers must be destroyed by incineration. Any residual seed or propagable material recovered during the process of cleaning must be rendered non-viable by heating, incineration or crushing.

5.4.2 Labelling of Containers

Primary containers should be labelled with an identifying number or name of the regulated LM plant material (*e.g.*, event name, number or other unique identifier) and the Dispatch Number found on the **Transport Record**.

All secondary containers used to transport LM plant material should be labelled to identify the Field Trial Manager and the recipient and their emergency contact details in case of an unintended release.

5.4.3 Accompanying Documentation for the Transport of LM Plant Material

The Field Trial Manager must provide complete information to be included in a **Transport Record**. This information will include: Contact details of Field Trial Manager and recipient; LM Plant Material Identification; Pre-Transport Details (rail, road, ship or air), his/her Signature and date of dispatch.

When multiple primary containers of regulated material are included within a single secondary container, a **Transport Inventory List** must be attached to the Transport Record. The Record of Transport, with attached Transport Inventory List (if applicable) must be sent (email/fax/letter) to the recipient before the consignment is sent.

The original Transport Record, with attached Transport Inventory List if applicable, must be placed within the secondary container by the Field Trial Manager. Copies of the Record of Transport, Transport Inventory List (if applicable) and other accompanying documents (*e.g.*, Phytosanitary Certificate) must be retained by the Field Trial Manager.

5.4.4 Receipt of Transported Goods

When a consignment of regulated, LM seed or propagable plant material is received, the following actions should be undertaken immediately by the recipient:

i. Confirmation/Verification that the Record of Transport and Transport Inventory List (if applicable) accompanied the consignment.

ii. If the Transport Record is absent from the consignment, the recipient must contact the Field Trial Manager and request that a copy be sent/transmitted immediately.

iii. Until such time as the Transport Record is received, the consignment must be placed in storage and no further action shall be taken. When the Record of Transport is received, the rest of the procedures shall be followed.

iv. The recipient shall complete the details regarding Receipt of Consignment section of the original Transport Record. A copy of the completed Record of Transport should be sent in writing (email or fax) by the recipient to the Field Trial Manager.

v. If the secondary container was damaged during transport, the recipient must ensure that the primary container was not damaged and that none of the plant material was lost by confirming the inventory of the consignment. If it is suspected that an unintended release has occurred, **the emergency response plan (Section 5.9) must be put into action immediately**.

5.5 FINAL HARVESTING

The final harvest of CFTs of experimental LM plants needs to be properly managed and involves the provision of SOPs that has to be designed for each particular LM plant taking into account the biology of the organism **(See application form, NBB/A/ER/10/FORM A)**. In general, the LM plants should be harvested in such a way as to prevent the unintended release of the events and their persistence at the trial site and to ensure that no plant material from the trial enters the human food or animal feed chains.

The following applies to termination of confined field trials:

i. When the experimental purpose of the field trial has ended, it must be terminated using methods approved by the NBB. This will depend on the type of LM plant and a specific SOP should be developed at the time of application.

ii. The NBB shall be notified **(no grace period as termination exercise**

is case specific, may also result from unforeseen circumstances) before termination and the notification shall indicate the exact time of the planned exercise.

iii. No LM plant materials should be taken out of the field trial site at the time of final harvesting or during the trial termination exercise without prior permission from the NBB.

5.5.1 Early Termination

In circumstances for example because of unfavourable environmental conditions (*e.g.*, flooding or drought) or because of compliance related considerations, a trial may have to be terminated before the planned final harvest date. LM plants from trials that are to be terminated early should be destroyed before seed-set (where applicable) and subsequently ploughed under or treated with appropriate concentrations of herbicides to render the plant material non-viable. Post-harvest restrictions (see Chapter 6) will apply immediately upon trial termination.

5.6 DISPOSAL OF PLANT MATERIAL AT THE END OF THE FIELD TRIAL

Plant material from a trial site that is not retained for research purposes, such as unwanted seeds, grain, roots, stalk, flowers, fruits and leaves have to be rendered non-viable by a suitable method as **approved by the NBB**.

This will require the development of SOPs specific to plant type and availability of facilities for disposal at the trial site as specified in **Section B3 (Waste Treatment Plan)** of the Risk Management information in the application form **(NBB/A/ER/10/FORM A)**.

Where material has to be removed from the trial site to a facility for subsequent analysis, storage or immediate disposal (*e.g.*, incineration, autoclaving), the material should be appropriately contained and transported according to the guidelines stipulated in Section 5.4. However while secure containment is strictly required, no separation of material as stipulated in section 5.4.1.1 is necessary.

5.7 MONITORING OF EXPERIMENTAL TRIAL SITE AFTER HARVESTING

Please refer to section 6.4 for guidelines on post-harvest monitoring.

5.8 CLEANING OF EQUIPMENT

i. All equipment used to harvest the trial should be cleaned at the trial site to eliminate the unintended transport and release of experimental LM plant material.

ii. Residual plant material recovered during the process of cleaning field equipment at the trial site should be rendered non-viable and disposed off a suitable method as approved by the NBB as in Section 5.6.

5.9 EMERGENCY RESPONSE PLAN

The following is in relation to **NBB/A/ER/10/FORM A Part C item no. 80**.

i. In the event of a confirmed unintended release of an approved LM seed or propagable plant material during post-harvest storage or transport, all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by a means **approved by the NBB**.

ii. The location of the unintended release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed off by a suitable method as approved by the NBB. The period of monitoring will be determined in consultation with the NBB.

iii. The unintended release incident shall be immediately documented in a **Record of Corrective Action**. The original Record of Corrective Action is to be retained by the PI and copies will be submitted in writing to the Field Trial Manager, recipient, IBC and the NBB. Any other corrective actions will be determined in consultation with NBB.

iv. The PI's IBC should be notified within 24 hours, and the NBB should be notified within 48 hours of the unintended release (refer to incident reporting form, IBC/IR/10/ANNEX3).

5.10 RECORD KEEPING

Central to a successful CFT is the scientific and legal need to ensure that all information is duly recorded and that clear, authentic, complete and secure records can be accessed when necessary. All activities related to sampling, on-trial harvest, final harvest, early termination, storage, transportation and disposal related to a CFT should be recorded immediately following completion of each activity and the records retained by the Field Trial Manager. Copies of the records should be forwarded to the PI and IBC.

The following documentations will be required:

i. *Storage*: An inventory of all LM plant material in storage and of any material removed from the storage area, dates and the purpose for removal shall be recorded. A daily record of the movement of material into or out of the storage area shall be kept and verified by

the Field Trial Manager or a designated person at the end of each day. A daily security log will also be provided. (See Section 5.4).

ii. *Transportation*: Records shall contain a description of the material transported, method and dates of transport and authorized custody (see Section 5.4). All movement of the LM plant material shall properly be recorded. Communications between the Field Trial Manager, the transporter and the recipient shall also be recorded. (See Section 5.4).

iii. *Material confinement*: A record of all activities carried out to ensure material confinement shall be kept, including the site map, site security, log book for entry and exit, personnel training, planting, and cleaning of equipment and disposal of excess to avoid removal of any LM planting material from the trial site.

v. *Harvesting*: A record shall document the amounts and fate of all harvested material including storage for subsequent analysis or the disposal of any unwanted LM plant material.

vi. *Unintended release* of LM plant material: A record of all activities related to unintended release including corrective actions taken and communications shall be kept. All records must be retained by the Field Trial Manager and must be made available for inspection by the IBC, Department of Biosafety or its authorized enforcement officers. (See Section 5.9)

POST-HARVEST MANAGEMENT OF CONFINED FIELD TRIALS

CHAPTER 6

6.1 INTRODUCTION

Post-harvest management prescribes how land planted with CFTs can be used in the year(s) following a trial harvest. These post-harvest measures are designed to ensure that any volunteers emerging after the final harvest are eliminated from the trial site, to prevent the establishment of the experimental LM events and to ensure that no experimental LM plant material is allowed to enter the human food or animal feed chains. . The mandated post-harvest restriction period will be dependent on the LM plant type and will be defined by the NBB on approval of the application.

6.2 SCOPE

This section provides a general guideline applied to all CFTs of LM plants for practices that can be undertaken to contribute to the safe management of trial sites after final harvest and during the mandated post-harvest period. Specific SOPs for different LM plant types will have to be developed based on these guidelines and approved by the NBB. The SOPs are developed in compliance to Part IV Section 9(2) of the **Biosafety (Approval and Notification) Regulations 2010** and information required in the application form **(NBB/A/ER/10/FORM A)**.

6.3 POST-HARVEST REQUIREMENTS AND RESTRICTIONS

i. During the post-harvest period, CFT sites cannot be used as pasture for animal grazing as regulated plants may be present as volunteers. The mandatory post-harvest restriction period (one or more years) for trial sites is LM plant specific and will be indicated by the NBB in the letter of approval for the CFT. The period of restriction is dependent on accurate and complete information on the biology of the LMO plant as provided for by the applicant.

ii. The post-harvest restriction period begins immediately upon final harvest or termination of the CFT at the trial site. During the post-harvest restriction period, all prohibited plants, volunteers of the experimental events and any sexually compatible relatives, should be removed from the trial site before anthesis. These plants should be rendered non-viable and disposed off by a suitable method approved by the NBB. Monitoring for and destruction of prohibited plants also applies to the isolation distance around the trial site if reproductive isolation was breached during the trial. If any prohibited plants are permitted to flower, the post-harvest restriction period will be extended by an additional term equal to the original post-harvest restriction period.

iii. Ownership and/or control of the trial site must be secured by the PI or Approved Person for the post-harvest restriction period. This includes all necessary local land permits and permits from the Department of Agriculture. This assurance is to be obtained in writing and submitted to the NBB before the commencement of the trial.

iv. Only the trial site will be subject to land use restrictions and monitoring during the post-harvest restriction period, with the following exception: when a breach of reproductive isolation was determined to have occurred in any adjacent area during the field trial period the isolation area will also be subjected to land use restrictions and monitoring during the post-harvest period.

v. Post-harvest monitoring and related activities must be recorded in a Post-harvest Monitoring Record Book.

vi. After completion of the post-harvest restriction period, the trial site may be planted with the same experimental event or another experimental event of the same plant species. The trial site will be subjected to the same regulations and/or permit conditions as the previous CFT (unless additional conditions are added by NBB. Post-harvest restrictions are then applicable after the final harvest of the subsequent CFTs.

vii. The trial site may also be planted with a conventional variety of the same plant species as the LM plant event. The trial site will be subjected to the same regulations and/or permit conditions as the previous confined field trial. All of the conventional plant material harvested from the trial site during the period of post-harvest restrictions will have to be handled in the same way as the experimental modern biotech-derived plant material because of the potential of adventitious presence of the experimental plant. Post-harvest restrictions are then applied after harvest of the subsequent CFTs.

6.4 POST-HARVEST MONITORING OF EXPERIMENTAL TRIAL SITE

i. During the post-harvest period, the Field Trial Manager and the PI must ensure that the trial site is monitored for the presence of volunteers or other prohibited plants at a frequency stipulated by the NBB.

ii. **Guard Rows**

In cases where guard rows have been used as a measure of reproductive isolation, the area of the guard rows is considered to be part of the trial site.

iii. **Growth stage**

At the time of monitoring, the growth stage of any volunteers and/or prohibited plants will be recorded (in the Post-Harvest Monitoring Record). To facilitate this, a growth stage key specific to the LM plant should be made available to the monitoring personnel to facilitate consistency in identifying growth stages. Growth stages will be specific to each LM plant and will be submitted with the information on the parent organism as in section A2 of the application form **(NBB/A/ER/10/FORM A)** which appeared in Appendix 1.

iv. **Breach of Spatial Isolation during the Confined Field Trial**

Where there has been an established breach of spatial reproductive isolation distance during the trial—where prohibited plants have been allowed to flower within the spatial isolation distance—the spatial isolation distance shall also be subject to post-harvest restriction and monitoring requirements.

v. **Destruction of Volunteers**

Volunteers shall be destroyed before flowering, and shall be disposed off within the trial site in a manner that prevents consumption by humans or livestock as prescribed in Section 5.6. If volunteers are allowed to flower within the trial site, this constitutes a serious breach of compliance.

vi. If prohibited plants are present in the spatial isolation distance at the time of flowering of the volunteers, and there is a possibility that they may have cross-pollinated with the volunteers, then the emergency response plan must be put into action immediately (see Section 6.5). The approved person shall be liable to any damage due to any incident of non-compliance.

Please refer to Appendix 1, Part B Risk Management, B1 Information on Control monitoring, post release plans to provide information on Post-Harvest Monitoring of Experimental Trial Site.

6.5 EMERGENCY RESPONSE PLAN

The following is in relation to NBB/A/ER/10/FORM A items no. 90 to 93

i. In the event of a confirmed unintended release of regulated LM plant material, all attempts shall be made to recover as much of the regulated material as possible. The recovered material will be rendered rendered non-viable and disposed off by a suitable method as approved by the NBB. If transportation is required for disposal of the regulated LM plant material please refer to Section 5.4.).

ii. The PI's IBC should be notified by the Field Trial Manager or PI within 24 hours, and the NBB should be notified within 48 hours of the unintended release (refer to incident reporting form, IBC/IR/10/ANNEX3).

iii. If an unintended release affects an area outside the perimeter of the trial site, that location will be marked, monitored and treated in the same manner as the trial site with respect to ensuring that no additional release of plant material occurs. The period of monitoring will be determined in consultation with the NBB.

iv. The unintended release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the PI and copies will be submitted by email and mail to the IBC and NBB.

v. Any other corrective actions will be determined in consultation with NBB.

Waste treatment plans should be established according to the needs of each CFT, taking into consideration the factors outlined in B2 Waste Treatment Plan of application form (NBB/A/ER/10/FORM A) which appeared in Appendix 1.

6.6 RECORD KEEPING

i. The Post-Harvest Monitoring Record will be completed by the Field Trial Manager for the duration of the post-harvest period.

ii. All records associated with the management of CFTs must be available for inspection by the IBC, Department of Biosafety or its authorized enforcement officers.

iii. At the end of the post-harvest restriction period when all

requirements for management of the CFT site have been completed, the original copies of all reports related to the trial site will be forwarded to the IBC for record and archive. Copies of all the reports shall be forwarded to the NBB.

iv. The PI or the Approved Person will archive copies of the following records for all permitted field trials for a minimum of six (6) years, whether or not the regulated LM plant is authorized for unconfined field trials or commercial release. This includes Record of Post-Harvest Restriction Monitoring, Record of Corrective Action (when applicable) and all other related records as in Section 5.10.

GLOSSARY

Anthesis: The time when a flower, plant or crop releases pollen.

Applicant: A party submitting an Application for a Confined Field Trial. Typically, the Applicant is the same as the Approved Person.

Approval: means an approval granted under the subsection 16(3) of the Biosafety Act 2007.

Approved Person: a) a person to whom an approval has been granted under Part III of the Biosafety Act 2007; or b) a person to whom an acknowledgement of receipt on the submission of a notification under Part IV of the Biosafety Act 2007 has been issued.

Compliance: Fulfilling the requirements of the Terms and Conditions of Approval, especially with regard to confinement measures.

Confined Field Trial (CFT): A small scale experimental field trial of LM plants to collect data necessary for an environmental risk assessment, 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 for a defined period of time for the purpose of mitigating impact on surrounding environment.

Confinement: Restriction of an organism and its genetic traits to a specific and defined area of the environment and for a defined period of time, herein called the 'confined field trial site' or the 'trial site'.

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

Facility Manager: The individual responsible for the supervision of a storage or testing facility.

Field Trial Manager: The individual(s) at a particular trial site, designated by the approved person as responsible for management and compliance of an authorized confined field trial. Field Trial Managers

are authorized to complete and sign documentation, forms and notes for the Trial file.

Following Crop: A crop planted on a trial site after harvest or termination of a confined field trial.

Free-Living: A plant living outside cultivation, or surviving without human intervention.

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

Living modified organism: Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living modified plant: Any living plant that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Material Confinement: Measures taken to ensure that LM plant material is not consumed by humans, livestock or animals.

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

Principal investigator (PI): PI is involved in conducting modern biotechnology research in an organization/institution. The PI is accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety.

Prohibited Plants: Plants that are sexually compatible with the LM plants being grown under confinement and are thus prohibited from the established spatial isolation distance of a confined field trial.

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

Reproductive Isolation: Measures taken to prevent, principally, pollen-mediated gene flow from plants in the trial site to nearby sexually compatible species. Also known as 'genetic confinement'.

Sexually Compatible: Capable of cross-pollinating and forming viable progenies / hybrids without human intervention.

Standard Operating Procedure (SOP): An established, written method or set of methods that describes how to routinely perform a given task.

Trait: A genetically determined characteristic.

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

Unintended release: Any unauthorised release of experimental modern biotech-derived plant material into the environment beyond the approved confined field trial area, including into the human food and/or livestock feed chains.

Variety: Subdivision of a species for taxonomic classification. Used interchangeably with the term cultivar to denote a uniform, stable group of individuals that is genetically and possibly morphologically distinct from other groups of individuals in the species.

Volunteers: Progeny arising from the plants in a confined field trial site.

REFERENCES

1. CropLife (2005). Compliance Management of confined field trials of genetically engineered plants.
2. Fischoff D, Bowdish K, Perlak F, Marrone P, McCormick S, Niedemeyer J, Dean D, Kussno, Kretzmer k, Meyer E, Rochester D, Rodgers S, Fraley R (1987) Insect tolerant transgenic tomato plants. Biotechnology 5: 807-813.
3. Malaysian Biosafety Act 2007 (Act 678)
4. Malaysian Biosafety (Approval and Notification) Regulations 2010

APPENDIX 1

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM A

APPROVAL FOR RELEASE ACTIVITIES OF LIVING MODIFIED ORGANISM (LMO) (RESEARCH AND DEVELOPMENT PURPOSES IN ALL FIELD EXPERIMENTS) OR IMPORTATION OF LMO THAT IS HIGHER PLANT

NBB/A/ER/10/FORM A shall be submitted to the Director General as an application for certificate of approval of release of LMO [Research and development purposes in all field experiments - Second Schedule of the Act - 1] or importation of living modified organism (LMO) that is a higher plant (not for contained use activities). Any organization undertaking modern biotechnology research and development shall submit the form through its registered Institutional Biosafety Committee (IBC). The IBC should assess the information in the form prior to submission. Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

Accuracy of information
The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

Confidentiality
Any information within this application which is to be treated as CBI, as described in the Biosafety Act 2007 in section 59(3) should be clearly marked “CBI” in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization
Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

NBB REF NO :
(For Office Use)

For further information
Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:
The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

Please retain a copy of your completed form.

NBB REF NO :
(For Office Use)

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM A is completed with relevant signatures obtained	☐
2. Application assessed and to be sent through the IBC	☐
3. A copy of clearance documents from the Department of Agriculture included (if required)	☐
4. A copy of the clearance document from the state office where the release is to take place	☐
5. Any information to be treated as confidential business information should be clearly marked “CBI” in the application	☐
6. 1 original copy and 6 copies of the completed application submitted. A soft copy of the submitted application (including all supporting documents/ attachments, if any) that do not contain any CBI.	☐
7. Fees as prescribed in the regulation: RM _____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title/ Unique Identification Code:	
5. IBC Project Identification No:	
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/application. II) How is this application different from the previous notification/application submitted for this activity? (please provide an attachment if additional space is required)	

NBB REF NO :
(For Office Use)

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

Institutional Biosafety Committee (IBC) Assessment Report for release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities).

This must be completed by the registered IBC of the Applicant's organization

Section A – IBC Details

1.	Name of organization:			
2.	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

Section B – IBC Assessment

3.	Name of principal investigator:	
4.	Project Title:	
5.	Date of the IBC Assessment:	
6.	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in the field experiment with the LMO have adequate training and experience for the task?	☐ Yes ☐ No
7.	The following information related to this project has been checked and approved	
	a) The objective of the project	☐ Yes ☐ No
	b) The description and genetics of the LMO	☐ Yes ☐ No

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	c) The risk assessment and risk management, taking into account the risks to the health and safety of people and the environment from the release of the LMO.	☐ Yes ☐ No
	d) The emergency response plan	☐ Yes ☐ No
8.	Has the information been checked by the IBC and found to be complete?	☐ Yes ☐ No
9.	Has the IBC assessed the proposed project? ☐ Yes ☐ No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.	

Signatures and Statutory Declaration

The proposed release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities) has been assessed as above and endorsed by the IBC. We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

IBC Chairperson:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBB REF NO :
(For Office Use)

Part A Risk Assessment

A1 General Information

1. Project Title.

2. Rationale of Project.

3. Project objectives:
   a) Overall Objective
   b) Specific Objective

4. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)

5. Release site(s) :
   (If more than one location is involved, then the information required in numbers 5, 6, 7, 8 & 9, 10, 11) should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place

6. Scale of release per release site.
   (Number of LMO involved, size of plot/site etc)

7. Date when the release(s) is expected to commence.

8. Frequency of releases.

9. Date when release(s) is expected to end.

10. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA).

11. Description of the proposed activities with the LMO.

12. Name of person(s) authorized to undertake activities with the LMO.

A2 Risk Assessment Information - Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

13. Details of the parent organism
    If the LMO is the result of a crossing event between more than one species/cultivar/breeding line/variety please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Cultivar/Breeding line/Variety
    f) Common name

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14. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

15. Information concerning the reproduction of the parent organism:
    a) The mode or modes of reproduction
    b) Any specific factors affecting reproduction
    c) Generation time

16 Information regarding the sexual compatibility of the parent organism with other cultivated or wild plant species.

17. Information concerning the survivability of the parent organism:
    a) Ability to form structures for survival or dormancy including seeds, spores and sclerotia
    b) Any specific factors affecting survivability, for example seasonability

18. Information concerning the dissemination of the parent organism:
    a) The means and extent of dissemination
    b) Any specific factors affecting dissemination

19. Details of the natural habitat of the parent organism and its range.

20. Is the parent organism exotic in Malaysia?

    ☐ Yes ☐ No

21. Is the parent organism naturalized in Malaysia?

    ☐ Yes ☐ No

22. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release(s)?
    (If more than one location is involved, then the information required in numbers 22 & 23 should be repeated for each location(s) of release)

    ☐ Yes ☐ No

23. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

24. The potentially significant interactions of the parent organism with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

25. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

26. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

27. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

28. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

29. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

30. Details of the modified trait(s) and how the genetic modification will change the phenotype of the LMO to be released.

31. What are the gene(s) responsible for the modified trait(s)?

32. Give details of the organism(s) from which the gene(s) of interest is derived:
(If more than one gene is involved then the information required in numbers 32, 33, 34, 35, 36 and 37 should be repeated for each gene)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Cultivar/Breeding line/Variety
    f) Common name

33. Indicate whether it is a:
    a) viroid
    b) RNA virus
    c) DNA virus
    d) bacterium
    e) fungus
    f) animal
    g) plant
    h) other (please specify)

34. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

35. Please provide the following information about the gene(s) of interest(s):
    a) Size of sequence of the gene(s) of interest inserted
    b) Sequence of the gene(s)of interest inserted
    c) Intended function of the gene(s) of interest
    d) Number of copies of the gene(s) of interest in the construct
    e) Details of the steps involved in the construction
    f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

36. Please provide the following information about the deleted sequence(s):
    a) Size of the deleted sequence(s)
    b) Function of the deleted sequence(s)
    c) Details of the steps involved in the deletion of sequences from the parental organism
    d) Provide the map(s) of construct(s)

37. The following information is on the expression of the gene(s) of interest:
    a) Level of expression of the gene(s) of interest and methods used for its characterization
    b) The parts of the plant where the gene(s) of interest is expressed, such as roots, stem or pollen
    c) Indicate the part(s) of the vector(s) that remains in the LMO
    d) The genetic stability of the gene(s) of interest

38. A description of the methods used for the genetic modification:
    a) How gene(s) of interest was introduced into the parent organism, or
    b) How a sequence of a gene was deleted from the parent organism

39. If no vector was used for the genetic modification please provide details of how the gene(s) of interest is introduced.

40. If vector(s) was used, please provide the following information:
    (If more than one vector was used, then the information required in 40 should be repeated for each vector).
    a) Type of vector
        i. plasmid
        ii. bacteriophage
        iii. virus
        iv. cosmid
        v. phasmid
        vi. transposable element
        vii. other, please specify
    b) Identity of the vector(s)
    c) Information on the degree of which the vector(s) contains sequences whose product or function is not known
    d) Host range of the vector(s)
    e) Potential pathogenicity of the vector(s)
    f) The sequence of transposons and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

41. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences of the detection of the inserted gene(s) including marker gene(s).

42. Information (biological features) on how the LMO differs from the parent organism in the following respects:
    a) Mode(s) and/or the rate of reproduction
    b) Dissemination

43. If there is any possibility that the inserted gene(s) in the LMO could be integrated into other species at the release site(s) and the surrounding environment and if so, please provide the following details:
    a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
    b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
    c) Any possible adverse effects of the transfer including
        i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)
        ii. Environmental risks posed by such an advantage

44. The identification and description of the target organism(s), if any.

45. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

46. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

47. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

48. Details of any other possible adverse consequences.

49. Details whether the LMO compared to the parent organism that will confer a selective advantage that can impact on survival in the release site(s), including a statement on how stable those features are.

50. Details of whether the modified trait(s) will confer a selective advantage on the LMO compared to the parent organism and if so, the nature of the advantages including a statement on how stable those features are and under what conditions.

51. Details of whether the gene(s) of interest or any part of the vector(s) has the ability to reproduce or transfer to other hosts and, if so, details of the host range.

52. In relation to human health:
    a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
    b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
    c) The capacity of the organisms for colonization
    d) If the organisms are pathogenic to immunocompetent persons:
        i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence,
        ii. communicability,
        iii. infective dose,
        iv. host range and possibility of alteration,
        v. possibility of survival outside of human host,
        vi. presence of vectors or means of dissemination,
        vii. biological stability,
        viii. antibiotic-resistance patterns,
        ix. allergenicity, and
        x. availability of appropriate therapies.

53. Details of unintended pleiotropic effects (if any), including undesirable effects on agronomic characteristics of the plant which may result from the expression of the gene of interest(s) in the LMO (for example, reduced fertility, increased prevalence, production losses, grain shedding), including an indication of the likelihood of these events.

54. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

55. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

56. Details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population:
    a) Details of pollen viability for the parent organism and of the LMO
    b) Details of any potential pollinators and their range and distribution in Malaysia

c) Quantitative data on successful cross-pollination between the parent organism, the LMO and its wild relatives, if available

A4 Information about weeds

57. Details of the members of the family of parent organism that are known to be weeds in any environment.

58. Details of cross-pollination between the species to which the LMO belongs and wild relatives known to be weeds, including a copy of any literature reports that support the information.

A5 Information about the seeds of the LMO

59. A statement on whether the LMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release.

60. If the LMO is to be allowed to set seed, will the mature seed normally remain contained within an ear, capsule or pod, so that practically all of the seed can be readily harvested, or is the seed shed soon after it matures?
If the latter, provide an indication of the proportion of seed likely to remain in the release site(s) following harvest.

61. Details of the length of time that the seeds are capable of being dormant and whether it differs from the parent organism.

A6 Characteristics affecting survival of LMO

62. The predicted habitat of the LMO.

63. The biological features which affect survival, multiplication and dispersal.

64. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

65. The sensitivity to specific agents (e.g. disinfectant, pesticides, fertilizers, wind, water).

A7 Information about any secondary ecological effects that might result from the release

66. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of parasites

A8 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

67. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the genetic modification.

A9 Information about resistance of the LMO to a biological agent

68. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A10 Information relating to the release site(s)

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

69. The size of the proposed release site(s).

70. The location of the proposed release site(s). Provide site map(s) with national grid reference(s).

71. Details of the reasons for the choice of the release site(s).

72. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of the LMO and transportation of the LMO, to or from the release site(s).

73. The preparation of the release site(s) before the release(s).

74. The methods to be used for the release(s).

75. The quantity of the LMO to be released.

76. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

77. The size of local human population.

78. The local economic activities which are based on the natural resources of the area.

79. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

80. The flora and fauna, including crops, livestock and migratory species in the release site(s).

81. The comparison of the natural habitat of the parent organism(s) with the proposed release site(s).

82. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Part B Risk Management

B1 Information on control, monitoring, post-release plans

83. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

84. Details of the proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

85. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:
    a) The survival or presence of the LMO, or transferred genetic material, beyond the proposed release site(s), including specificity, sensitivity and reliability of detection methods
    b) Impacts on the characteristics, or abundance, of other species

c) Transfer of the gene(s) of interest to other species
d) Any other hazards or deleterious effect

86. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

87. Details of ongoing monitoring to be undertaken after the release(s) are completed.

88. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

89. The methods for elimination or inactivation of the organisms at the end of the experiment and the measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

90. Type of waste generated.

91. Expected amount of waste.

92. Possible risks resulting from the waste.

93. Description of waste treatment envisaged and its disposal.

Part C Emergency response plan

94. Methods and procedures for controlling/removing the LMO in case of unintentional release or any adverse effects being realized.

95. Methods for isolation of the area affected.

96. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects

Part D Data or results from any previous release(s) of the LMO

97. Give the following information from the previous applications and releases of the LMO for which the applicant is seeking an approval:
    i. Reference number of each application
    ii. Date of the certificate of approval issued
    iii. Terms and conditions (if any) attached to the approval
    iv. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
    v. Relevant data if the previous release is on a different scale or into a different ecosystem
    vi. Any other relevant details

98. Details of results of any applications made for approval of the LMO in other countries, including information about conditions (if any) attached to the approval.

99. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in this present application has been developed.

100. If the LMO has been previously released overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.