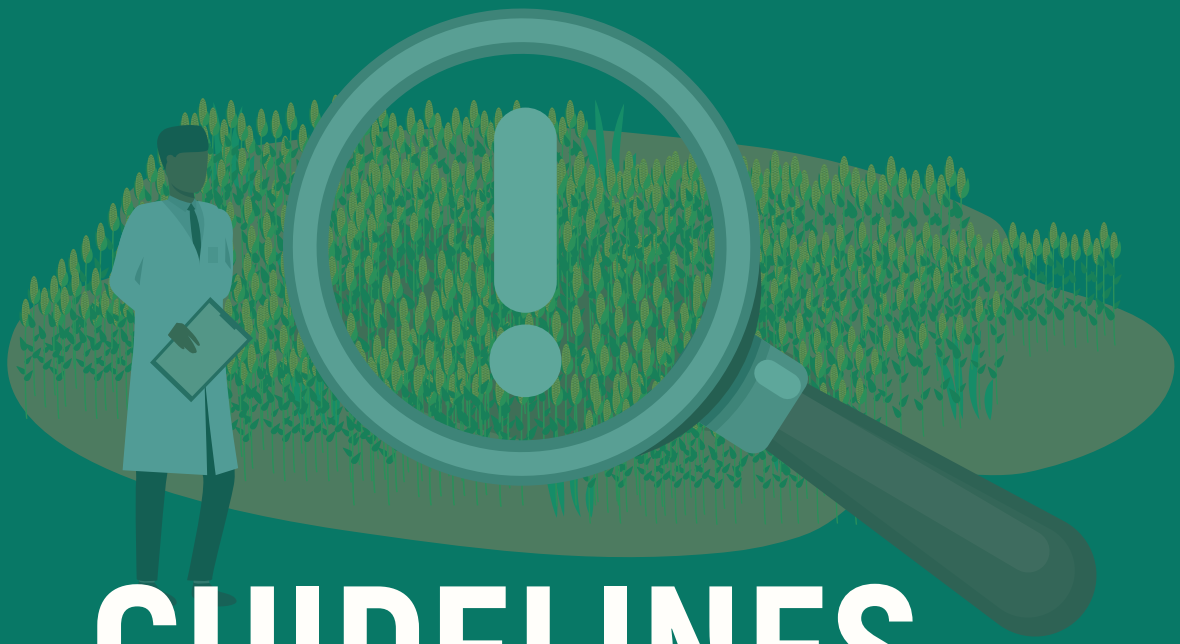

GUIDELINES

FOR THE CONDUCT OF CONFINED FIELD TRIALS OF GENETICALLY MODIFIED PLANTS IN SRI LANKA

Ministry of Environment, Sri Lanka

2021

Guidelines for the conduct of confined field trials of genetically modified plants in Sri Lanka

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1. Introduction

Genetically Modified (GM) plants arising from research in contained laboratories have to be progressively tested before their commercialization. The next stage after evaluation under contained facilities, i.e. laboratories/ greenhouse, is testing them in small experimental field trial sites in confined conditions referred to as "Confined Field Trials or CFTs". CFTs are conducted under conditions intended to mitigate the establishment, spread and persistence in the environment, of seed or of other reproductive genetic material as well as any interaction of the genetic material with the environment. The main objective of CFTs is to collect data about the new agronomic properties conferred by genetic modification and to generate information/data for estimating the potential impact to the environment including risks to animal and human health. CFTs therefore provide an opportunity to the researchers to collect information, characterize and evaluate GM plants. This information is critical for the risk assessment required by the regulatory authorities when submitting an application for approval for environmental release or commercialization.

Sri Lanka is a Party to the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity and has developed a National Biosafety Framework (NBF) in 2005. Sri Lanka is committed to regulate activities involving GMOs, also referred to as Living Modified Organisms (LMOs) resulting from modern biotechnology to ensure their safe use. In this context, The "Guidelines for the conduct of confined field trials of GM plants in Sri Lanka" have been prepared to provide guidance on the process of applications and authorization for the conduct of CFTs of GM plants in Sri Lanka.

2. Scope

These guidelines are applicable to GM plants, whether imported or developed domestically, intended for testing in confined field trials.

These guidelines do not apply to

- the unconfined environmental release of GM plants or their commercial release,
- the environmental dissemination of other types of GMOs (e.g., recombinant microorganisms, GM fish, GM animals),
- GM plant material, including derived products (e.g., flour, corn starch, crushed meal, oil), for direct use in food, feed, or processing.

These guidelines are intended to provide guidance to applicants on appropriate risk management procedures to be implemented during the conduct of CFTs of GM plants in Sri Lanka. These guidelines are not intended to explicitly define all the requirements for the conduct of confined field trials, as further terms and conditions/requirements may be identified during the review process by the National Competent Authority (NCA) in Sri Lanka.

[1] Living Modified organism: Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; LMOs are considered to be synonymous with genetically modified organisms (GMOs).

[2] Modern biotechnology: The application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

3. Key definitions

The definitions below apply to these guidelines for conduct of CFTs of GM plants.

Application: An application is the information/data package in prescribed format submitted for each regulated genetically engineered event intended for cultivation in a confined field trial. Multiple events of a single plant species may be included in a single application provided they have been transformed with the same construct.

Authorization Letter: A letter issued by NCA to authorize conduct of any research experiment on GM plants under specified terms and conditions.

Authorized Party: The applicant or designated agent will be considered the authorized party' or the purposes of authorization of confined field trial and is the person who shall accept responsibility for compliance with the terms and conditions of the permit. The authorized party may designate a trial in-charge, who will be responsible for ensuring compliance with the requirements of authorization as specified by the NCA.

Breach: Any contravention or violation of any term and/or condition of authorization of a confined field trial will be considered a breach under these Guidelines.

Compliance: Fulfilling the requirements of the terms and conditions of authorization, especially with regard to confinement measures.

Event: A genotype produced from the transformation of a single plant species using a specific genetic construct. For example, two lines of the same plant species transformed with the same or different constructs constitute two events.

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 GM plant material.

Prohibited Plant: Plants of any species that are sexually compatible with the regulated plant under field conditions, including volunteers that may arise in the isolation area during the conduct of confined field trials.

Trial In-Charge: The technical person designated by the authorized party as responsible for management of the field trial, ensuring compliance with the terms and conditions of a confined field trial authorization and providing information required by NCA. The trial in-charge must, at a minimum, be an agriculture graduate.

Trial Protocol: The protocol for conducting a confined field trial approved by the NCA.

Trial Site: The area where one or more confined field trials of the same plant species may be grown.

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

4. Regulatory authorities

The Central Environment Authority under The Ministry of Environment (MoE) is the NCA for the implementation of biosafety regulations involving GMOs/LMOs in Sri Lanka. MoE has set up a National Coordinating Committee for Biosafety (NCCB) for overseeing activities involving GMOs/ LMOs. NCCB consists of members from concerned ministries, experts and representatives from relevant institutions of Sri Lanka. There are five government departments that serve as the Sectoral Competent Authorities (SCAs) viz., (i) Department of Animal Production and Health, (ii) Department of Fisheries and Aquatic Resources, (iii) Department of Agriculture, (iv) Department of Health Services, and (v) Department of Wildlife Conservation. The SCAs are considered as expert/technical bodies for risk assessment and risk management

5. Contained vs. confined conditions

The differences between research conducted under "contained" and "confined" conditions are described below:

i. Contained conditions refer to work with LMOs, including plants, within contained facilities, such as a laboratory, a greenhouse, a nethouse, and areas used for the storage and handling of experimental LMOs. Under contained conditions, there is a physical barrier or barriers that contain material under research and development so there is virtually no direct contact of viable LMOs with the environment.

ii. Confined field trial is a field experiment of growing a GM plant in the environment under specified terms and conditions that are intended to mitigate the establishment and spread of the plant.

The key considerations for conduct of confined field trials of GM plant include:

i. It is of limited size, typically carried out on a small scale, often one hectare or less.

ii. It is an experimental activity conducted to collect data, including data regarding potential biosafety impacts. Additionally, field trials are carried out to produce sufficient planting materials so that the developer can undertake research to address the information and data requirements for livestock feed and human food safety assessments.

iii. The confined field trial is conducted under conditions known to mitigate:
- Pollen- or seed-mediated dissemination of the experimental plant;
- Persistence of the GM plant or its progeny in the environment, and
- Introduction of the GM plant or plant products into the human food or livestock feed pathways.

iv. Access to the field site is restricted to authorized personnel. The site may be on a restricted-access government facility, such as an experimental station. Where necessary, a fence with a lockable gate may be installed to restrict access to the site.

v. The measures for confinement are set forth in detail in the terms and conditions of authorization of the confined trial, and must be strictly followed by the authorized party and trial personnel.

vi. The regulatory authority maintains surveillance over the trial by means of inspections and by reports required from the authorized party on the conduct of the trials

6. Risk mitigation measures for confined field trials

The risk mitigation measures to ensure the safe conduct of confined field trials are as follows:

6.1 Preventing the dissemination of new genes

The confined field trial must be managed in a manner that prevents the dissemination of GM plant material into the environment. This is accomplished by imposing conditions of reproductive isolation on all plants within the confined trial site, so as to prevent the unintentional movement of pollens from plants in the trial to neighbouring plants of the same crop species and/or a sexually compatible species. It is important to remember that for pollen-mediated gene flow and introgression to occur, a number of conditions must be satisfied: the two plants must be 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 are followed. Spatial isolation from sexually compatible plant is the basic method of reproductive isolation used for all plant species based on appropriate distances already documented. Other measures used may include removal of flowers, bagging of flowers/tassels to prevent open pollination, termination of the trial prior to flowering, 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).

6.2 Preventing persistence in the environment

It is necessary that GM plants, or its progeny, will not persist in the environment at the end of the confined field trial. Any viable progeny plant materials (volunteers) in subsequent growing seasons have to be managed to prevent persistence in the environment. Therefore, a post-harvest period is established for each plant species during which planting of the same or a sexually compatible plant species is prevented and active monitoring is 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.

6.3 Preventing introduction into the food and feed pathways

A major critical control point in the proper management of confined field trials is the prevention of the introduction of GM plant materials into food or feed pathways. 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 and the storage of seed and other plant material. Residual or excess plant material on the trial site, and any material retained after the harvest has to be disposed. Measures have to be also in place to control unlawful harvest from the trial site.

7. Information for confined field trial application

7.1 Submission of the application

An applicant must be:

- A permanent resident of Sri Lanka
- Accept full responsibility for regulatory compliance in line with the specific terms and conditions set for authorization
- Responsible for the all cost(s) incurred towards any remedial actions required in the event of an accidental release of GM plant material and at time of termination for disposal of the GM plant material
- Liable to legal actions in case of non-compliance with the conditions stipulated for authorization

Application Form, as prescribed by NCA is to seek authorization for confined field trials. Submission of the application shall be channeled by all applicants through the respective Institutional Biosafety Committees (IBSCs), whose role is to verify availability of the proposed facilities before endorsing and forwarding the application to the NCA.

7.2 Process of review and authorization

Application forms for new confined field trials and renewals of previously authorized confined field trials of GM plants are required to be submitted to the NCA for review and receipt of authorization.

Applications for a confined field trial must be received at least 90 working days in advance of the proposed trial start date. The NCA 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.

NCA shall forward the application for scientific review to SCA to carry out a science-based assessment and forward its recommendation on whether or not the application should be approved and the terms and conditions to be imposed by the NCA, if any, after the assessment. After having considered the recommendations of the SCA, the comments of the relevant department or agency, the views of members of the public, if any, and any additional information, the NCA may grant the application by issuing an authorization letter or refuse the application.

Where authorization is granted, an authorization letter shall be issued consisting of the following elements:

i. The effective date from which authorization/approval is granted and the confined field trial may commence. The term of the authorization is limited to one year from the effective date, unless a longer term is specifically requested and authorized.

ii. An authorization code to be used on all subsequent correspondence relating to the confined field trial.

iii. The terms and conditions under which authorization is granted, including the requirements for transportation and storage, reproductive isolation and site monitoring, harvesting, and post-harvest land use restriction.

Where the authorization is denied, the applicant is informed of the reason(s) and provided with an opportunity to reapply or appeal.

Renewal of authorization for a confined field trial may be considered for trials with the same crop, trial site(s) and phenotypic trait as previously authorized. The process for submission and authorization of a renewal shall be the same as described in the sections above for a new application.

Even though the specific terms and conditions of authorization for renewal required shall be the same as in previous years, the NCA reserves the right to modify, add, or remove any ondition of authorization upon renewal.

7.3 Completing the application form

Applicants for a new confined field trial or a renewal must use the application form provided in Annex-I. The following considerations should be kept in mind when completing the information requirements:

Part-A: Application type

Applications may be new or renewals or supplementary. For renewals, the previous confined field trials authorization code must be included and the rest of the application must be identical to the original application. A supplementary application is one that contains additional information to address a previous deficiency identified by the NCA.

Part-B: Applicant and part-C: designated authorized signatory (AS)

The applicant must be a permanent resident of Sri Lanka, or must designate an authorized agent who should be a permanent resident of Sri Lanka. For foreign applicants, both Part-B and Part-C must be completed. For Sri Lankan applicants, completion of Part-C is not required.

Part-D: Unmodified plant species

Information on the unmodified plant species, particularly its reproductive biology, is critical to designing appropriate terms and conditions to ensure reproductive isolation of the confined field trial.

The Applicant may prepare a document on baseline biological information of the unmodified plant with a focus on reproductive biology, the information on the unmodified species and submit to NCA along with the completed application for a confined field trial.

Part-E: Information on the GM plant

Sufficient information about the GM plant must be provided to allow a determination of whether the standard conditions of reproductive isolation for the plant species are applicable, if supplementary conditions are necessary, or if adequate reproductive isolation can be ensured under any set of conditions.

Specifically, the applicant shall provide a detailed description of the source of all introduced sequences, including promoters, enhancers, polyadenylation and termination signal sequences, coding regions, marker or antibiotic resistance gene(s), and other non-coding sequences. Applications must also describe the origin of any vectors/vector agents and transformation methods, including the possibility of transferring any pathogenicity-related genes into the GM plant.

If there is any likelihood that introduced genetic material may be mobilized out of the GM plant by a mechanism other than normal sexual reproduction, this should be described and data, if available, on the frequency and species of potential recipient organisms, should be provided. Such horizontal gene transfer issue would be addressed by the NCA with the help of various experts before denying or granting approvals.

If there is any likelihood that the introduced genetic material encodes a protein that is toxic to non-target species, including animals and humans, or is allergenic to humans, this must be identified.

In addition, if the genetic modification was intended to alter any aspect of the reproductive biology, compositional, stress tolerance or any other specific characteristic of the plant, (e.g., seed dormancy, seed viability, germination rate, pollen dispersal, seed dispersal, vegetative dispersal, salt and drought tolerance, nutritional enhancement, etc.), this must be described.

Part-F: Information on the trial site

Information on the trial site must include contact information for the technical person responsible for the conduct of the confined field trial, normally the trial in-charge, as well as contact information for the person responsible for the trial site during the post-harvest period, if it is not the trial in-charge. These persons must be permanent residents of Sri Lanka.

At the time of application, information must be provided on the size of the confined trial(s) and location of the confined trial site including state, district and divisional secretary's division. The application must also provide information on the trial site habitat, including proximity to any protected areas or the presence of any endangered or threatened indigenous species, or any non-target species that could be affected by the confined field trial.

A detailed map of the trial site must be submitted to the NCA, preferably 7 working days before sowing/planting and certainly within 7 working days after sowing/planting of the trial site (see 7.5).

The application must indicate the anticipated post-harvest land use of the trial site including anticipated follow-on crop and how trial site boundaries shall be marked during the post-harvest period in order to facilitate inspection.

Part-G: The trial protocol

The trial protocol includes information on the purpose of the confined field trial and type of data to be collected, and information on trial management including activities associated with reproductive isolation, planting, pesticide application, harvest, monitoring, and emergency response plan in the event of an accidental release. Any proposed methods of reproductive isolation or monitoring shall be subject to supplementary conditions imposed by NCA on a case-by-case basis.

If the Applicant desires to retain any seed or other plant material from the confined field trial, or transport said material from the trial site, this must be indicated in the trial protocol (Part-H.8.3, 8.4) and authorized by NCA. In the absence of such authorization, all plant material derived from the confined field trial, including seed, shall be destroyed on the trial site using a method as directed by NCA in the authorization letter.

Part-H: Applicant/authorized party verification

All correspondence with respect to the application, including the notification of authorization/ permit, will be addressed to the applicant, if a resident of Sri Lanka, or the designated agent, if the applicant is a non-resident. In the event of authorization, this person shall be the authorized party for the purposes of conduct of the confined field trial. The authorized party assumes full responsibility for compliance with all terms and conditions of authorization, including all legal and financial responsibility associated with any compliance, breach, etc. Acknowledgment of this responsibility is indicated by the signature in Part-D.

For applications that are submitted electronically, either by electronic mail, facsimile transmission, or on some other electronic media, the original signed application must be received by NCA prior to the granting of an authorization for a confined field trial.

7.4 Confidential business information

In situations where completion of the application would entail the disclosure of confidential business information (CBI) or trade secrets, a CBI and a CBI-deleted application must be submitted. The CBI-deleted copy should be an exact copy of the CBI application except where confidential texts have been deleted. Each CBI application page containing confidential information should be marked “CBI”. This term “CBI” must be placed in the right hand margin next to the CBI material and the term “CBI COPY” must be placed at the top right hand side of all pages containing CBI.

If an application does not contain CBI, then only one copy of the application is required.

In the CBI-deleted application, the point of deletion of the CBI material must be marked with brackets to indicate that said material was removed and the term “CBI-deleted” must be placed in the right hand margin next to the empty brackets. The term “CBI-DELETED” must be placed at the top right hand side of all pages from which CBI material was deleted.

For information claimed as CBI, the applicant must provide a written justification. Published literature usually cannot be claimed as CBI. Applicants should bear in mind that the national competent authority may provide copies of the CBI-deleted to other institutions for their review, and if insufficient information is present in CBI-deleted copy, it may hinder the provision of comments or concurrence with the competent national authority’s initial review.

7.5 Trial site maps

Submission of a detailed map of the confined field trial is a condition of authorization, and if one is not provided with the application, it must be received by the NCA within seven (7) working days from the completion of planting at the trial site. In the event this latter requirement is not met, the NCA reserves the right to cancel the authorization and require destruction of the confined field trial. The provision of draft maps at the time of application is recommended as this will facilitate the assessment.

Maps of confined field trials must be legible and precise. Maps should be on a blank page with crisp line drawings and block letters. Maps on lined or graph paper, photocopies of road or topographical maps will not be accepted. On each map, the following information must be clearly printed:

i. The general location of the field trial (city/town/region).

ii. Compass directions, with North at the top of the page.

iii. The legal land location.

iv. Measurements between the trial site and permanent surrounding landmarks, i.e. the exact trial location coordinate. Permanent markers must be placed to identify the confined trial boundaries. When this is not possible, measurements from permanent surrounding landmarks must be provided for precise location of the site, both for current year and post-harvest restriction periods.

v. Exact trial dimensions and an indication of surrounding crops, particularly those that may lie within the spatial isolation distance. When applicable, show previous years trial site locations on the map(s).

vi. The name, phone number and e-mail address of the trial manager or field contact.

vii. The confined field trial authorization code provided by the NCA (for maps submitted after planting).

viii. The planting date of the trial.

8. Conduct of confined field trials

8.1 Applicant responsibility

It is the sole responsibility of the Authorized Party to ensure compliance with all the terms and conditions stipulated in the authorization letter. This responsibility extends to cover the actions of any sub-contractors, co-operators or any agencies/persons/farmers that may work on the trial site for the purpose of establishing and maintaining the trial site as well as during the process of handling GM plant material even during termination.

The onus is on the authorized party to ensure that the confined field trial will comply with all conditions without breach.

8.2 Trial site size and number

Confined field trials provide developers with the opportunity to evaluate the performance of these plants, to collect biosafety data needed to meet regulatory requirements for commercial release and to produce material needed for food and feed safety assessments. To ensure that confined field trials are conducted for research purposes and not commercial activities, confined field trials shall be subject to restriction in size and number, unless the Applicant applies for an exemption.

Confined field trials are limited to no more than:

- 1 hectare per trial site,
- 10 trial sites per submission (includes locations submitted in new applications and renewal of authorizations),
- 10 hectares cumulative per submission.

Exemptions on trial size and the number of site locations may be granted in case where a valid scientific research rationale is submitted by the applicant and considered by the regulatory authorities would be considered only based on scientific rationale.

The suitability of the trial site proposed by applicant will be evaluated taking into account the considerations about the location, presence of sexually compatible species, proximity to protected areas, endangered/ protected species.

8.3 Reproductive isolation of confined field trials

As indicated in section 5, to prevent their establishment and spread within the environment, GM plants within a confined trial must be reproductively isolated from sexually compatible plant species in proximity to the trial site. In addition, any progeny plants that arise on the trial site after completion of the trial must be eliminated.

It is the responsibility of the authorized party to ensure that the conditions for reproductive isolation of all trial plants are met during both the current growing season and the post-harvest period.

8.3.1 Spatial isolation

The primary means of achieving reproductive isolation is through the imposition of a spatial isolation distance between the trial plants and any neighbouring sexually compatible plants. Minimum spatial isolation distances vary depending on the reproductive biology of the plant species and must ensure effective genetic confinement.

The spatial isolation distance must be continuous and completely enclose the confined trial field. Any prohibited plants (i.e. any plants sexually compatible with the GM plants undergoing trial) found growing within the isolation zone shall be removed prior to flowering, otherwise, a breach of reproductive isolation shall be deemed to have occurred. In the event of any breach of reproductive isolation, the post-harvest land use restrictions and requirements for post-harvest monitoring shall apply to both the trial area and the surrounding spatial isolation distance.

Applicants should consult with the NCA on minimum isolation distances and periods of post-harvest land use restriction for the plant species undergoing trial. The NCA reserves the right to increase the minimum spatial isolation distance for specific applications.

8.3.2 Alternative methods of reproductive isolation

Other methods that may be acceptable to reproductively isolate specific GM plants include:

a) Removal of floral parts before pollen maturity.

b) Bagging of flowers/tassels to prevent open pollination.

c) Termination of the trial prior to flowering.

d) Temporal isolation of pollination (i.e. planting earlier or later than any nearby sexually compatible plants).

e) Planting of pollen trap rows of conventional (non-regulated) plants of the same or similar variety as the GM variety to act as a pollen trap for insect-pollinated species.

When pollen trap rows are authorized as an alternative means of reproductive isolation, the authorized party shall ensure that the pollen trap row plants flower concurrently with the plants in the confined field trial. If any of the trial plants flower before the onset of flowering of pollen trap row plants, or if any of the trial plants have not completed flowering after the pollen row plants have completed this stage, a breach of pollen trap row isolation will have occurred. All plants within the pollen trap row area must be disposed of in the same manner as the GM plants in the trial. The pollen trap row area will be subject to the same conditions of post-harvest land use restriction and monitoring as the trial site.

Whenever an alternative means of ensuring reproductive isolation has been authorized, it is with the understanding that in the event of any failure of the alternative method (e.g., pollen-trap row failure because the trial plants flowered before the pollen-trap row plants), the reproductive isolation method shall revert to the spatial isolation distance. For this reason, the authorized party must have control over the spatial isolation distance surrounding a confined field trial even if an alternative method of reproductive isolation has been authorized. This control must take into account neighbouring fields and any financial implications to their owners.

8.3.3 Disposition of material from confined field trials

No harvested material or by-product from a confined field trial may be used as human food or livestock feed. Seed or other plant material harvested from confined trials (including pollen-trap rows) that has not been previously authorized by the NCA to be retained for future research work, must be disposed of by an approved method (e.g., dry heat, steam heat, incineration, deep burial, chemical treatment, or crushing). Composting is not an acceptable method for the disposal of plant material.

Progeny from any confined field trial cannot be retained for future planting without prior written authorization from the NCA, and this must be specifically requested in the field trial application.

8.3.4 Post-harvest land use restrictions and post-harvest monitoring

In addition to ensuring reproductive isolation during the growing season of the confined field trial, it is also necessary to prevent the establishment of any progeny plants at the field trial site during subsequent growing season(s). Therefore, the NCA should have established a post-harvest period for each plant species and require that the following precautions be implemented during this period:

a) The area under restriction must be monitored during the post-harvest period to ensure that any transgenic progenies are destroyed prior to flowering.

b) No plants of the same or a sexually compatible species may be planted in the restricted area during the post-harvest period.

c) Land use of the restricted area must be compatible with requirements for monitoring and removal of prohibited plants. No plants that could interfere with monitoring for prohibited plants can be planted.

The restricted area is normally limited to the area of the trial site proper, including the pollen-trap row area (if pollen-trap rows were used as an alternative method of reproductive isolation) and does not include the surrounding spatial isolation distance. However, if a breach of reproductive isolation occurred during the performance of the confined field trial, the restricted area will include the trial site and the surrounding spatial isolation distance.

9. Standard terms and conditions of authorization instead of General terms and conditions of authorization

The following terms and conditions shall apply to all CFTs and shall be appended to each letter of authorization:

a) The authorized party shall ensure that GM seed and plant material for planting are transported in clearly identified, secure containers and kept separate from other seed and plant material. All packing material, shipping containers, and any other material accompanying the GM plant material shall be treated or disposed of in such a manner as to prevent the dissemination and establishment of this material or any progeny plants.

b) In the case of accidental release or spillage of GM plant material during transport, recoverable seeds or seedlings shall be collected and destroyed, the site shall be marked and monitored and oral notification shall be immediately provided to the NCA. Any plants arising from unrecoverable seed or seedlings must be destroyed before flowering.

c) Any equipment or implements used during planting shall be cleaned on the trial site prior to movement off the site in order to remove residual plant material. Surplus seed, transplants, or other plant material remaining after planting, or recovered during the cleaning of equipment, shall be destroyed using an approved method, such as: dry heat, steam heat, incineration, crushing, deep burial, or chemical treatment.

d) A planting notification shall be submitted to the NCA within seven (7) working days following the completion of planting at a trial site. An indicative application has been attached as Annex-I. This notification must also include a detailed map of the trial site if it was not provided with the original application.

e) The authorized party shall maintain adequate records of all confined field trials, including current season and post-harvest site monitoring activities related to trial site compliance (including subcontracts), cleaning of equipment, transportation, and disposition and storage of all surplus and harvested seed and plant material.

f) No seed or other plant material from the confined field trial may enter the human food or animal feed chain.

g) Harvested seed and plant material from the confined trial may only be retained if requested in the application and previously authorized by the NCA. Any harvested seed and any plant material must be clearly labelled, securely transported, and stored separately from other seed or plant material.

h) A record of harvest attached as Annex-III documenting the date and method of harvest, the amount of harvested materials, the disposition of harvested materials, the cleaning of any equipment used during harvest, and the method of destruction of any residual plant material on the trial site, shall be prepared by the authorized party for verification and signature by an inspector authorized by NCA. This harvest inspection shall occur either during harvest or within five (5) working days of the completion of harvest.

i) The authorized party shall notify the NCA in writing at least thirty (30) days in advance of planting any plant species on the trial site during the post-harvest period.

j) The authorized party shall submit a report summarizing the completed trial, including observations and data, methods of observation, and analysis of any deleterious effects on plants, non-target organisms, or the environment, to the NCA within six (6) months after the termination of the confined field trial.

k) An inspector designated by NCA shall be allowed access, during regular business hours, to the place where GM plant material is located and to any records relating to the transportation, storage, or use of the GM plant material in a confined field trial.

l) If a chemical treatment is used on the trial site that requires a time until safe re-entry, a sign must be posted at the access to the trial indicating the date and time of spraying as well as the time until safe re-entry. This condition is intended to protect the health and safety of inspectors and workers.

m) The NCA shall be notified within the time periods and manner specified below, in the event of the following occurrences:

i. Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of GM plant material.

ii. In writing as soon as possible but not later than within five (5) working days if the GM plant is found to have characteristics substantially different from those listed in the application or suffers any unusual occurrence.

Supplementary terms and conditions of authorization specific to the GM plant species identified in the application may also be included in the notification of authorization.

9.1 Records and Reporting

9.1.1 Record keeping

Adequate records are critical to establish the regulatory compliance of the authorized party with these guidelines and other relevant requirements. Clear, authentic and readily accessible records shall be maintained and documented. Records of confined field trials include current season and post-harvest site monitoring, activities related to trial site compliance (including subcontracts), cleaning of equipment, transportation, disposition and storage of all surplus and harvested seed and plant material, that shall be maintained by the Authorized Party. All of these shall be made available to NCA or the designated monitoring agencies upon request. Records can be maintained in electronic format, but a paper copy must be made available to the NCA upon request.

9.1.2 Records required and reporting

Mandatory records required by NCA include:

- **Planting information:** NCA shall be informed in writing within 7 working days of planting at a trial site. A Record of Planting shall be submitted and must reference the confined trial permit number, document the amount of material planted, the planting date, the transportation of plant material to the trial site, the cleaning of any equipment used during planting, and the disposition of any surplus plant material remaining after planting. If it was not provided with the application, this notification must also include a detailed map of the trial site.
- **Harvest information:** A record of harvest/termination shall be prepared for each confined field trial site and shall document the date and method of harvest, the amount of harvested material, the disposition of any harvested materials, the cleaning of any equipment used during harvest, and the method of destruction of any residual plant material on the trial site. This record must be submitted within 15 days of the harvest or completion of the trial. Formats of the record of planting and record of harvest are placed at Annex-II and Annex-III. In addition, the applicant may maintain the records to document the following activities.
- Transportation of seed or other plant material to the trial site for planting, or from the trial site after the harvest. This would include a description of the material transported, method of transport and information of responsible parties,
- Storage of all planting material, including surplus material remaining after planting. This would include amount of material, planted at the trial site, the quantity of any surplus material, method of its disposition,
- Actions relating to ensuring reproductive isolation at the trial site during both the current growing season and the post-harvest period. Depending on the methods of isolation prescribed in the authorization, this may include
  - monitoring for and removal of prohibited plants within the spatial isolation distance
  - recording growth stages of trial plants or plants within a pollen trap row area
  - de-flowering or bagging or destruction of trial plants
- Records of any unauthorized or accidental release of GM traits or plant material, including corrective actions taken or planned, and
- Additional records may be required depending on specific circumstance

Applicants must keep a separate log book for each trial site, during the current and post-harvest years of the trials. Log books and records must be kept for 7 years after the end of the post-harvest land use restrictions of a trial site. Until the end of the post-harvest restrictions period, a copy of these trial site records must be kept by the field manager at the trial site and/or by the person in charge of the storage location and/or the person in charge of the disposal of seed or propagable material in order to facilitate the inspection of the records, disposal and storage by NCA designated inspectors.

A report summarizing the completed trials and experimental data, including any amendments to the original protocol, must also be made available to the NCA upon request. All plant material used on, or harvested from, the trial must be accounted for.

9.2 Contingency plan

The Authorized Party will establish a contingency plan for actions to be taken in case of emergency, or of unauthorized or accidental release of GM plant material.

REFERENCES AND ADDITIONAL INFORMATION

African Biosafety Network of Expertise (ABNE), NEPAD (2015) Frequently asked questions and general information: Confined Field Trials of genetically modified crops: key considerations. *http://nepad-abne.net/confined-field-trials/*

CFIA (2011) Directive 2000-07: Conducting confined research field trials of Plant with Novel Traits in Canada. Canadian Food Inspection Agency (CFIA), Ottawa
https://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/

DBT and MoEFCC (2008) Guidelines & Standard Operating Procedures (SOPs) for confined field trials of regulated, genetically engineered plants, Department of Biotechnology (DBT), Ministry of Science and Technology and Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India. *http://geacindia.gov.in/resource-documents*

FAO (2011) Module D: Test and Post Release Monitoring of genetically modified organisms, Biosafety Resource Book., Oliver Brandenberg et al., Food and Agriculture Organization (FAO) *http://www.fao.org/3/i1905e/i1905e03.pdf*

Monitoring Confined Field Trials of Regulated Genetically Engineered (GE), 2015. Plants, Phase-II Capacity Building Project on Biosafety. Ministry of Environment, Forest and Climate Change. *http://geacindia.gov.in/resource-documents.aspx*

Ministry of Environment and Forests (MOEF), Guidelines for Monitoring Confined field trial of genetically engineered plants in Bangladesh. Govt. of the People's Republic of Bangladesh. *https://bangladeshbiosafety.org/*

MoEFCC (2015) Monitoring Manual: Monitoring Confined Field Trials of Regulated genetically engineered plants, Phase II Capacity Building Project on Biosafety. Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India. Accessible at *http://geacindia.gov.in/resource-documents*

OGTR (2009) Application for licence for dealings with a GMO involving intentional release of the GMO into the environment (DIR) Office of the Gene Technology Regulator (OGTR), Canberra ACT at *http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dirclass-2*

SCBD (2000) Cartagena protocol on biosafety to the convention on biological diversity: Text and Annexes. Secretariat of the Convention on Biological Diversity (SCBD), Montreal
https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

USDA (2017) Permit user's guide with special guidance for epermits. United States Department of Agriculture (USDA), Riverdale,
https://www.aphis.usda.govbiotechnology/downloads/permit_guidance.pdf

Annex-I

Application form for confined field trials of Genetically Modified (GM) plants

This application form must be completed for each plant species x trait combination of a GM plant species proposed for testing in a confined field trial. More than one hybrid or variety of transgenic event of a single plant species may be included in a single application. When derived plants of more than one individual genetic construct are proposed for trial, a separate copy of Part E of the form must be submitted for each construct. For example, in the case of genetic modifications to the same plant species intended to confer the same phenotypic characteristic (e.g., insect resistance) but employing different introduced cry genes, then a separate Part E must be completed for each cry gene construct.

In the same way, when the same genetic construct of a LM plant is proposed for confined field trial testing at more than one geographic location, a separate Part F of this application must be completed for each trial site location.

All sections of this application must be completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in this application.

Copies of scientific publications or articles should not be attached to this application form unless they specifically meet an information requirement.

If completion of this application requires the disclosure of confidential business information (CBI), then both CBI and non-CBI copies of the application must be submitted. Applications must be received by the NCA at least 60 days in advance of any proposed trial.

Application Form for confined field trials of Genetically Modified (GM) plants

PART A. APPLICATION TYPE ("✓" one box)

☐ New request ☐ Supplementary ☐ Renewal

_____

(If renewal, enter previous trial code from letter of authorisation)

PART B. APPLICANT	
Name:	
Organisation:	
Address:	
Telephone:	
E-mail:	
Fax:	
Citizenship:	

PART C. DESIGNATED AGENT	
Name:	
Organisation:	
Address:	
Telephone:	
E-mail:	
Fax:	
Citizenship:	

PART D. INFORMATION ON THE UNMODIFIED PLANT SPECIES	
D.1 Latin name:	D.2 Common name:
D.3 Biology document for the plant species is:	☐ Attached ☐ Published by the Executive Secretariat
D.4 Is the plant species a known pest in Sri Lanka or elsewhere?	☐ Yes ☐ No (If Yes, list any locations below)
D.5 Are there significant free-living populations of the plant species in Sri Lanka?	☐ Yes ☐ No (If Yes, list any locations below)
D.6 Are there sexually compatible wild relatives of the plant species in Sri Lanka?	☐ Yes ☐ No (If Yes, list any locations below)
D.7 Known centres of origin of the plant species:	
D.8 Known centres of genetic diversity of the plant species:	
D.9 Main mechanism of pollen dispersal:	☐ Wind borne ☐ Insects (list species below)
D.10 Mechanisms of natural seed dispersal:	☐ None ☐ Birds ☐ Wind ☐ Other wildlife (Provide other details below, if necessary)
D.11 Seed dormancy (including tubers):	☐ <= 1 yr ☐ <=2 yr ☐ > 2 yr
D.12 Is the plant species considered to be weedy or naturally invasive?	☐ Yes ☐ No
D.13 Is the plant species known to be a source of substances toxic to humans or animals?	☐ Yes ☐ No (If Yes, identify the compounds, the levels that induce toxicity, and the affected species.)
D.14 Is the plant species known to be a source of human allergens?	☐ Yes ☐ No (If Yes, identify the allergenic protein(s)

PART E: INFORMATION ON THE GM PLANT

E.1 Name or designation of event:	Enter the identification code or event name for each transgenic event included in the plant genotype.

E.2 Category of genetic modification

- ☐ AP-agronomic properties
- ☐ BR-bacterial resistant
- ☐ FR-fungal resistant
- ☐ HT-herbicide tolerant
- ☐ IR-insect resistant
- ☐ MG-marker genes only
- ☐ NR-nematode resistant
- ☐ PQ-plant quality
- ☐ VR-virus resistant
- ☐ Other (specify below)

E.3 Was any plant material for use in the confined field trial imported? Import permit number: _____	☐ Yes ☐ No (If Yes, identify the Import Permit Number and date of importation below) Date of importation: _____
E.4 Plant phenotype	Enter a short phrase describing the plant phenotype (e.g., resistance to lepidopter on insects)
E.5 Has/have the event(s) previously been tested in Sri Lanka?	☐ Yes ☐ No (If Yes, enter the most recent trial authorisation code or permit number)
E.6 Has/have the event(s) previously been tested in other regions or countries outside Sri Lanka?	☐ Yes ☐ No (If Yes, list countries and year of approval and any applicable permit or notificatio numbers)
E.7 Has/have the event(s) received authorisation for unconfined release, or commercialisation, in countries outside Sri Lanka?	☐ Yes ☐ No (If Yes, enter the names of countries and year of approval)
E.8 Modification method	☐ AT-Agrobacterium mediated transformation ☐ PF-protoplast fusion ☐ BT-Biolistic and particle gun transformation ☐ OO-other (describe below)
E.9 Selection method used in plant regeneration	☐ AR-antibiotic resistant ☐ HT-herbicide tolerant ☐ SU-substrate utilization ☐ OO-other

E.10-1 Information on the introduced DNA Source plasmid name:	☐ PL-Intact plasmid ☐ RF-DNA fragment
E.10-2 Is the plasmid and/or construct map attached?	☐ Yes ☐ No
E.10-3 Is the introduced DNA known to result in any infections agents?	☐ Yes ☐ No (If Yes, provide further details, below)
E.10-4 Does the introduced DNA contain any sequences derived from known human or animal pathogens?	☐ Yes ☐ No (If Yes, provide further details, below)

E.10-5 Briefly describe the derivation of the transformation vector or transforming DNA:

E.10-6 Provide information for each genetic element (or feature) of the construct and transformation vector, including coding and antisense sequences, promoters, enhancers, termination and polyadenylation signal sequences.

Starting Pos (bp)	Ending Pos (bp)	Size (kb)	Name	Donor Organism	Species Name	Donor Organism Source of Toxins or Allergens? (Yes/No)	Protein Expressed? (Yes/No)	Trait Category (see F2)

E.11-1 Indicate the intended site of integration of the introduced DNA:	☐ Nuclear genome ☐ Chloroplast genome ☐ Mitochondrial genome ☐ Transposable element ☐ Extra chromosomal plasmid ☐ Viral vector ☐ Other (describe below)
E.11-2 Indicate how stable integration of the inserted DNA was demonstrated:	☐ Mendelian segregation of introduced trait, within a generation ☐ Multi-generational stability of introduced trait ☐ Other (describe below)

E.12 Provide the following information for each anticipated protein product of the introduced DNA.

Name	Mode of Expression	Is the Protein Known to be an Allergen?	Is the Protein Known to be Toxic to Humans or Non-target Organisms?
	☐ CS-constitutive ☐ TS-tissue specific ☐ IN-inducible ☐ DS-development specific	☐ Yes ☐ No	☐ Yes ☐ No

If any of the newly expressed proteins are known to be allergens or toxic to humans or non-target organisms, provide further details below.

E.13 INTENDED OR ANTICIPATED CHANGES TO PLANT CHARACTERISTICS

E.13-1 Is the genetic modification intended to alter plant weediness?	☐ Yes ☐ No (If Yes, provide further details, below)
E.13-2 Is the genetic modification intended to alter seed dormancy, survivability, or germination rate?	☐ Yes ☐ No (If Yes, provide further details, below)
E.13-3 Is the genetic modification intended to alter pollen dispersal?	☐ Yes ☐ No (If Yes, provide further details, below)
E.13-4 Is the genetic modification intended to alter seed dispersal?	☐ Yes ☐ No (If Yes, provide further details, below)
E.13-5 Is the genetic modification intended to alter vegetative dispersal?	☐ Yes ☐ No (If Yes, provide further details, below)

PART F: INFORMATION ON THE TRIAL SITE

F.1 Provide the name, address, and contact i nformation for the Trial Manager:

Name:	
Organisation:	
Address:	
Telephone:	
E-mail:	
Fax:	

F.2-1 Site location code:	F.2-2 Number of trials at this location:
F.2-3 Trial size (ha or m2):	F.2-4 Distance to nearest crop of the same plant species (m):
F.2-5 Legal or descriptive land and/or GPS location:	
F.3 Has a completed map of the trial site been enclosed?	☐ Yes ☐ No (If No, a completed map must be provided within 7 working days following planting.)
F.**4 HABITAT** F.4-1 Is the trial site part of a managed ecosystem (i.e., agricultural land)?	☐ Yes ☐ No (If Yes, how close is the nearest natural ecosystem?)
F.4-2 Is there an area of special ecological interest (e.g., protected area, sanctuary) near the trial site?	☐ Yes ☐ No (If Yes, briefly describe, below)
F.5-1 Describe any sexually compatible wild or cultivated plant species that are in the vicinity of the trial site.	
F.5-2 Are there any endangered or threatened species on or near the trial site?	☐ Yes ☐ No (If Yes, briefly describe, below)

F.5-3 What mechanisms are in place to prevent local fauna from removing plant material from the trial site?

F.6-1 Provide the name and address of the person having control over the trial site during the post-harvest period, if different from above.

Name:	
Organisation:	
Address:	
Telephone:	
E-mail:	
Fax:	

F.6-2 What is the anticipated post-trial land use?

F.6-3 Describe how the trial site boundaries will be marked to facilitate subsequent inspection:

PART G: INFORMATION ON THE TRIAL PROTOCOL

G.1 Trial protocol (study) title:

G.2-1 Anticipated planting date: G.2-2 Anticipated harvest (termination) date:

G.3 Fully describe the purpose of the field trial, the experimental design and the nature and type of data to be collected. Please indicate any proposed herbicide or pesticide use.

G.4 REPRODUCTIVE ISOLATION

G.4-1 Check the primary method of reproductive isolation:

- ☐ Spatial isolation distance
- ☐ Detasseling and removal of floral parts
- ☐ Guard Rows ☐ Temporal Isolation
- ☐ Bagging and Tents
- ☐ Trial termination before flowering

G.4-2 Fully describe the reproductive isolation measures being implemented for this trial and give details:

G.5-1 Describe how GM seed and/or plant material will be packaged for transport:

G.5-2 Describe how shipping containers and/or packaging material will be sanitized and/or disposed of after use:

G.5-3 Describe how containers or packages containing regulated seed or plant material will be labelled:

G.5-4 Describe how chain of custody will be ensured during transport and the type of records that will be retained:

G.6 PLANTING

G.6-1 How will material be planted?

- ☐ Manually
- ☐ Mechanically

G.6-2 If any equipment or utensils are to be used during planting, explain how they will be cleaned on the trial site

G.6-3 Will any unmodified plants of the same or a related species be planted at the trial site location?

- ☐ Yes
- ☐ No

(If Yes, briefly describe why, below)

G.6-4 Describe how surplus planting material will be devitalized (destroyed) at the trial site:

G.6-5 Describe how quantities of seed planted and any excess will be recorded:

G.7 UNREGISTERED PESTICIDES

G.7-1 Will any unregistered pesticide be used on the trial site?

- ☐ Yes
- ☐ No

(If Yes, complete G.7-2 through G.7-5, below)

G.7-2 Name of the unregistered pesticide:

G.7-3 Active ingredient:

G.7-4 Number of applications per season:

G.7-5 Total area to be sprayed: (square meters)

G.8 HARVEST

G.8-1 Will plants be allowed to set seed?

- ☐ Yes
- ☐ No

G.8-2 How will plant material be harvested?

- ☐ Manually
- ☐ Mechanically (if mechanically, describe cleaning procedures, below)

G.8-3 Will any harvested plant material be retained from the trial?

- ☐ Yes
- ☐ No

(If Yes, briefly describe the purpose, below)

G.8-4 Provide the name and address of the person having control over the trial site during the post-harvest period, if different from above.

Name:	
Organisation:	
Address:	
Telephone:	
E-mail:	
Fax:	

G.8-5 Describe the storage method and storage location of harvested materials, if applicable.

G.**9 MONITORING THE TRIAL SITE**

G.9-1 Describe the extent and frequency of trial site monitoring during the current growing season:

G.9-2 Describe what monitoring results will be recorded:

G.9-3 If any controlled monitoring protocols are proposed (e.g., planting of unmodified plants of a related species to determine the possibility and frequency of gene flow), describe these:

G.**10 CONTINGENCY PLANS**

G10-1 Describe your contingency plans in the event of an accidental release of regulated seed or plant material or a breach of reproductive isolation:

G.10-2 Describe your contingency plans in the event of an unexpected spread of regulated plant material after an accidental release:

PART H: APPLICANT AND AGENT VERIFICATION

This application is submitted in accordance with requirements specified in Guidelines for Conduct of Confined Field Trials of Genetically Modified (GM) Plants in Sri Lanka.

_____ _____

Signature of applicant and/or designated agent, as appropriate

Date

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief, and I accept full responsibility for compliance with all terms and conditions of authorisation, including all legal and financial responsibility associated with any compliance infractions.

FOR USE OF THE NATIONAL COMPETENT AUTHORITY ONLY

_____ _____

Date of application receipt

Date of administrative review completed

Application complete? ☐ Yes ☐ No

Application forwarded to Sectoral Component Authority? ☐ Yes ☐ No

(If Yes, please specify below:

Final determination: ☐ Authorised ☐ Denied

_____ _____

Effective date of decision

Field trial authorisation code

_____ _____

Signature of regulatory official

Date

Annex-II

RECORD OF PLANTING

INSTRUCTIONS:

- This Record of Planting should be completed to document the planting of all regulated plant material at a field trial site.
- Use the following two-letter codes to designate the destruction method for excess planting material: DH-dry heat, SH-steam heat, BU-burning, DB-deep burial, CR-crushing, OT-other.
- Following completion of this record by the Trial In-Charge, one copy should be forwarded to the Permitted Party. The original should be retained by the Trial In-Charge and made available to regulatory officials upon request.
- In the event of an Accidental Release during planting, the Permitted Party should be notified immediately by telephone and facsimile. The incident and any corrective action taken should be recorded on a Record of Corrective Action.

PLEASE PRINT CLEARLY

PERMITTED PARTY

Name .....
Organization .....
Address .....
Telephone ..... Fax .....
E-mail .....

TRIAL IN-CHARGE

Name .....
Organization .....
Address .....
Telephone ..... Fax .....
E-mail .....

RECORD OF PLANTING (cont'd)

TRIAL SITE

Site location .....

Trial site size (ha or m^2) .....No. of trials at this site.....

Legal or descriptive land location .....

Distance to nearest cultivated field of the same plant species (m) .....

Distance to nearest commercial crop of any kind (m) .....

Is the isolation distance under the Trial In-Charge's control? ☐ Yes ☐ No

PLANTING

Method of planting

☐ Hand
☐ Machinery
☐ Other, Describe Below

Was all machinery cleaned, inspected and confirmed free of plant material prior to exiting the trial site? ☐ Yes ☐ No

COMPLETE THE FOLLOWING SECTION FOR EACH TRIAL AT THE TRIAL SITE

S. No.	Event name	Permit number	Area planted	Date planted
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

RECORD OF PLANTING (cont'd)

TRIAL IN-CHARGE VERIFICATION

This activity has been carried out to meet the specific authorization permit conditions for conduct of confined field trials of regulated plant material.

.....	.....
Signature of Trial In-Charge (By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.)	Date signed

Annex-III

RECORD OF HARVEST / TERMINATION

INSTRUCTIONS:

- This Record of Harvest / Termination should be completed following harvest or termination of confined field trials and disposition of regulated plant material at a single trial site. It should document the method of harvesting the regulated plant material, the harvest date(s), and the fate of all harvested material and any residual regulated plant material remaining on the trial site.

- A copy of the Record of Harvest / Termination should be forwarded to the Permitted Party within FIVE (5) DAYS of harvest/termination of the trial. The original should be retained by the Trial In-Charge.

- In the event of an Accidental Release of regulated plant material during harvest, termination and/or disposition of the trial, the Permitted Party should be notified immediately by telephone and facsimile. The incident and any corrective action taken should be recorded on a Record of Corrective Action.

PLEASE PRINT CLEARLY

PERMITTED PARTY

Name .....
Organization .....
Address .....
Telephone ..... Fax .....
E-mail .....

TRIAL IN-CHARGE

Name .....
Organization .....
Address .....
Telephone ..... Fax .....
E-mail .....

RECORD OF HARVEST / TERMINATION (cont'd)

TRIAL SITE

Site location .....

Trial site size (ha or m2) .....No. of trials at this site.....

Distance to nearest cultivated field of the same plant species (m) .....

Distance to nearest commercial crop of any kind (m) .....

Is the isolation distance under the Trial In-Charge's control? ☐ Yes ☐ No

HARVEST / TERMINATION METHOD

Date of harvest / termination .....

Describe harvest / termination method

- ☐ Hand
- ☐ Machinery
- ☐ Burning
- ☐ Other, Describe Below

Machinery or tools inspected, cleaned and confirmed free of plant material prior to leaving the trial site? ☐ Yes ☐ No

Indicate how machinery was cleaned at the trial site following crop termination

- ☐ Hand
- ☐ Machinery
- ☐ Other, Describe Below

ON SITE DISPOSITION OF PLANT MATERIAL ☐ Burning ☐ Buried

RECORD OF HARVEST / TERMINATION (cont'd)

DATA SHEET FOR RECORDING HARVEST AND DISPOSITION

S. No.	Permit number	Amount harvested (g)	Quantity retained / stored (g)	Type of material retained	Regulated plant material transported from site
1.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
2.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
3.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
4.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
5.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
6.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
7.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
8.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
9.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No
10.				☐ grain/seed ☐ whole plant ☐ vegetative material	☐ Yes ☐ No

RECORD OF HARVEST / TERMINATION (cont'd)

ADDITIONAL COMMENTS AND OBSERVATIONS

.....
.....
.....

TRIAL IN-CHARGE VERIFICATION

This activity has been carried out to the specific authorization permit conditions for conduct of confined field trials of regulated plant material.

.....	.....
Signature of Trial In-Charge (By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.)	Date signed

National Focal Point and Coordinating Agency for Biosafety in accordance with the Cartagena Protocol in Sri Lanka

Ministry of Environment
Biodiversity Secretariat
"Sobadam Piyasa",416/C/1,
Robert Gunawardana Mawatha,
Battaramulla.
Sri Lanka.
Telephone : +94-11-2034100
Web: www.env.gov.lk
Email: sec@env.gov.lk