Guidelines & Standard Operating Procedures (SOPs) For Confined Field Trials of Regulated, Genetically Engineered (GE) Plants

Department of Biotechnology
Ministry of Science & Technology,
Government of India

Ministry of Environment and Forests
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FOREWORD

Regulation of genetically engineered (GE) crops is extremely important to address the biosafety concerns associated with these products. The Ministry of Environment and Forests (MoEF) and Department of Biotechnology (DBT) are responsible for implementing biosafety regulations within the country. As part of its mandate under regulatory framework of GMOs, DBT has framed guidelines for safety of recombinant DNA products in 1990 and guidelines for research in transgenic plants in 1998.

There have been significant advancements in the area of research and development of genetically engineered crops. These include targeting a variety of crops including cereals, vegetables, oilseeds etc. and incorporating traits such as insect resistance, herbicide tolerance, stress tolerance, nutritional enhancement, shelf life improvement etc. As part of the process of development, field testing of GE crops is undertaken under confined conditions that include maintaining an isolation distance and other measures to ensure reproductive isolation, site monitoring and post harvest land use restriction.

Confined field trials have been regularly conducted for almost twenty years across the world and more than 10 years in India. So far the regulatory system in India has effectively managed the approval process at various stages of development of Bt cotton, the only GE crop commercialized so far. However, with several crops under various stages of development, continuous improvement in the management of field trials is required in line with increasing knowledge in this area as well as to build public confidence in this technology. I am pleased to note that the Member Secretaries of the two apex regulatory bodies i.e. Dr. K.K. Tripathi from RCGM and Dr. Ranjini Warrier from GEAC have put in considerable efforts in putting together a harmonised set of new guidelines and standard operating procedures (SOPs) for the conduct of confined field trials. The guidelines have been reviewed by the members of RCGM and GEAC prior to their adoption. The views of various experts have been taken through series of consultations with State Agricultural Universities as well as by placing them on the websites. Biotech Consortium India Limited (BCIL) provided assistance in organizing series of regional consultations as well as finalization of the documents.

I believe these Guidelines and SOPs would make the regulatory process for field trials a harmonized and uniform process for all stakeholders. Regulations being a dynamic process, in line with the scientific developments, I hope that these guidelines and SOPs would be continuously updated from time to time.

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PREFACE

Government of India is committed to safe use of genetically modified organisms *(GMOs) and products thereof. A well defined regulatory framework for biosafety assessment of GMOs is in place under Environment (Protection) Act, 1986. Rules for the manufacture, use, import, export & storage of hazardous micro organisms, genetically engineered organisms or cells were notified in 1989 by the Ministry of Environment and Forests (MoEF) and a series of guidelines have been developed subsequently by DBT as per the regulatory mandate.

India approved the first genetically modified crop i.e. Bt cotton for commercial cultivation in 2002 after extensive testing and evaluation. As of now, there are several crops under various stages of research, development and field trials. The confined field trials of these genetically engineered (GE) crops are an important step in the research and development process as they allow the developers and regulators to obtain important environmental, human and animal safety information on the plants with introduced gene/event.

The present set of guidelines and standard operating procedures (SOPs) has been prepared jointly by MoEF and DBT to strengthen the management and monitoring of confined field trials of GE crops in the country. These guidelines supplement the "Guidelines for research in transgenic plants, 1998" and also are in line with commitments under the National Environment Policy, 2006 to periodically review the regulatory processes and guidelines for LMOs to ensure that these are based on current scientific knowledge.

I wish to put on record my appreciation for the sincere and untiring efforts put in by my colleagues Shri A. K. Goyal, Joint Secretary, MoEF and Vice Chairman, GEAC, Dr Ranjini Warrier, Director, MoEF and Member Secretary, GEAC and Dr K. K. Tripathi, Advisor, DBT and Member Secretary, RCGM in developing these documents. I also acknowledge the useful inputs provided by members of the GEAC and RCGM during the review process. The support provided by Dr O. P. Govila, Former Head, Deptt of Plant Breeding and Genetics, IARI and Dr Vibha Ahuja, Deputy General Manager, Biotech Consortium India Limited (BCIL) in finalizing the documents has been valuable.

I am sure that these guidelines and SOPs would serve as practical tools for researchers, policymakers and industry. The information provided, particularly technical guidance will help in ensuring safe and proper field trials of GE crops.

(B.S. Parsheera)

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PROLOGUE

As of now, Bt cotton is the only transgenic crop approved for commercial cultivation in the country. The apex regulatory bodies i.e. the Genetic Engineering Approval Committee (GEAC) and Review Committee on Genetic Manipulation (RCGM) had ensured safety assessment of Bt cotton through extensive field evaluation and testing across the country prior to its release. Elaborate guidelines and protocols were put in place for various stages/ types of field trials to be conducted under various agro climatic conditions.

Significant advancements in research and development of genetically engineered (GE) crops containing different gene/events have been made in the country and accordingly regulatory system has to deal with variety of GE crops integrated with multiple traits. The conduct of confined field trials of these new genetically engineered crops has to be undertaken under the terms and conditions that mitigate impacts on surrounding environment. Though considerable experience has been gained with the regulatory approval of Bt cotton, a need was felt to relook and consolidate various protocols and procedures developed so far.

Keeping the above in view, DBT and MoEF initiated an exercise to prepare guidelines and standard operating procedures(SOPs) for the conduct of confined field trials. These Guidelines supplement the "Guidelines for research in transgenic plants" prepared by DBT in 1998. A consultative approach was adopted to finalize the above mentioned documents through organizing a series of regional consultations and public review by placing them on the websites of MoEF and DBT http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html, http://dbtbiosafety.nic.in and www.igmoris.nic.in. The comments received from various stakeholders have been suitably incorporated. The 'Guidelines' were discussed by the regulatory committees' viz. MEC, RCGM and GEAC and then adopted in July 2008.

The objective of the Guidelines is to ensure that confined field trials are conducted under appropriately controlled conditions and in workable and efficient manner. A new application format has been designed to seek detailed information at the beginning of the process itself. The Standard Operating Procedures (SOPs) have been formulated to ensure quality and safety at each stage of a field trial, including transportation and storage of experimental GE plant material. Recording formats have been provided for proper and uniform documentation during the conduct of the trials. Although the present SOPs are generic and applicable for all crops, these would be supplemented by crop specific protocols for providing further guidance to the applicant and to ensure safety compliance. Crop specific biology documents are also under preparation. Extensive efforts will be undertaken to disseminate information about new guidelines by making them available on the websites as well organizing sensitization workshops. To start with, a series of training workshops is being organized in the State Agricultural Universities (SAUs) in 16 states, where the trials have been conducted / underway.

To keep pace with the advancements in developments in GE crops, it is proposed that guidelines and SOPs be reviewed at least once in two years and suitably updated.

Dr. Ranjini Warrier **Dr. K.K. Tripathi**

GUIDELINES FOR THE CONDUCT OF CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

1 INTRODUCTION

Field trials are an important component of the process for approval of a genetically engineered (GE) crop for commercial cultivation. These trials represent the first controlled introduction of a GE crop into the environment falling in between experiments in contained facilities and commercial release to farmers. "Guidelines for Research in Transgenic Crops, 1998" issued by the Department of Biotechnology (DBT) briefly describe the considerations for limited field experiments. In view of the enormous progress made during the last decade in the research and development of GE crops a need was felt to revisit these guidelines to streamline the procedures for the safe conduct of confined field trials and methodical evaluation of the same.

In this context, the "Guidelines for the conduct of confined field trials of regulated, GE plants in India" have been prepared to provide instructions to help applicants meet requirements for the application and authorization/ approval of confined field trials of regulated, GE plants under Rules for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells Rules, 1989 of the Environment (Protection) Act, 1986. These guidelines summarize the information requirements and procedures used by the two regulatory committees, the Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GEAC), that are responsible for evaluating and approving applications for confined field trials. The information provided in this document does not preclude additional regulatory requirements on case to case basis either from RCGM or GEAC or any other Ministries/regulatory bodies.

These Guidelines supplement the biosafety measures for field trials given in section 7 of the "Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998" published by DBT.

2 CONTAINED VS. CONFINED CONDITIONS

These Guidelines use specific terminology to differentiate between research conducted under "contained" and "confined" conditions as described below.

2.1 Contained Conditions

Contained conditions refer to work with GE organisms within contained facilities, such as a laboratory, a greenhouse, a nethouse, and areas used for the storage and handling of experimental GE organisms. 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 GE organisms with the environment. Activities carried out within such contained facilities are generally performed subject to specific biosafety guidelines and under specified levels of containment as detailed in Guidelines for Research in Transgenic Plants, 1998, wherein three different categories of containment levels have been defined for genetic engineering experiments on plants. These guidelines are primarily based on guidelines on containment issued by OECD.

2.2 Confined Field Trial

A confined field trial is a field experiment of growing a regulated, GE plant in the environment under specified terms and conditions that are intended to mitigate the establishment and spread of the plant. A single confined

field trial may be comprised of one or more events of a single plant species that are subject to the same terms and conditions of confinement which include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. It is understood that the experimental plant/species/varieties/hybrids grown in confined trials are those that have yet to receive regulatory approval for environmental release from GEAC. This confinement is also to be understood in terms of confinement of a particular GE plant in a particular region, state, village or a research farm of the applicant and is not accessible by other parts of the country in environmental terms.

Embodied in this definition of confinement are three important considerations. Firstly, confined field trials are typically carried out on a small scale, usually to a maximum of one hectare (ha). There may be exceptions to this *e.g.*, the cultivation of larger areas so that sufficient plant material may be harvested for livestock feeding trials. Secondly, a confined trial is an experimental activity conducted to collect data on potential biosafety impacts. The collection of such field trial data is a prerequisite for safety assessment of the GE crop under evaluation. Additionally, field trials are carried out to produce sufficient plant material so that the developer can undertake research to address the information and data requirements for livestock feed and human food safety assessments.

Finally, the trial is conducted under conditions known to mitigate:

1. Pollen- or seed-mediated dissemination of the experimental plant;
2. Persistence of the GE plant or its progeny in the environment, and;
3. Introduction of the GE plant or plant products into the human food or livestock feed pathways.

As it is generally used within this document, “confinement” of a field trial refers to reproductive isolation, but depending on circumstances, may also include some degree of physical isolation. On a case-by-case basis, specific methods of physical confinement may also be advisable to prevent herbivory or the destruction of plant material by foraging animals, or the unauthorized harvest or removal of plant material by humans.

3 REGULATORY AUTHORITIES

As mentioned above, the activities involving the use of GE organisms and products thereof are regulated under the “Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells” notified under the Environment (Protection) Act, 1986, commonly referred as Rules, 1989. These rules and regulations are implemented by the Ministry of Environment and Forests (MoEF) and Department of Biotechnology (DBT) and State Governments. Six competent authorities and their composition have been provided for in the Rules to handle various aspects *i.e.*, Recombinant DNA Advisory Committee (RDAC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Approval Committee (GEAC), Institutional Biosafety Committee (IBSC) attached to every organization engaged in rDNA research, State Biotechnology Coordination Committee (SBCC) and District Level Committees (DLCs). While the RDAC is advisory in function, the IBSC, RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes. In addition to the above, a Monitoring cum Evaluation Committee (MEC) has been set up by the RCGM to monitor the field performance of GE crops.

The initial assessment of an application for a confined field trial begins at the institutional level itself. Based on information generated by the applicant in the laboratory and the greenhouse[1], an application is made to the IBSC for permission to conduct a confined field trial. The IBSC evaluates the proposal for conducting a field trial and, if recommended by the IBSC, the applicant may submit the application to RCGM.

[1]During the course of product development it is common and desirable to undertake event selection in the field under confined conditions. Typically, this includes planting small plots comprised of several to dozens of events of the same plant species so that a preliminary phenotypic evaluation can be completed to facilitate the selection of one to a few events for further evaluation. Such trials (often referred to as strip trials) would be permitted as Event Selection trials by RCGM but these cannot be counted towards the three years of trials that are a prerequisite to GEAC approval.

RCGM, functioning in the DBT, is the Regulatory Authority for **Biosafety Research Level I (BRLI) trials**. These trials are limited in size to no more than 1 acre (0.4 ha) per trial site location and a maximum cumulative total of 20 acres (8.1 ha) for all locations for each plant species/construct combination (*e.g.*, one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.

GEAC, functioning in the MoEF, is the Regulatory Authority for **Biosafety Research Level II (BRLII) trials.** These are limited in size to no more than 2.5 acres (1 ha) per trial site location and number of locations to be decided on a case by case basis for each plant species/construct combination (*e.g.*, one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.

An application to GEAC for the environmental release of a new event will not be considered unless the Applicant has completed:

1. First crop season of confined field trials at the level of Biosafety Research Level I to be followed by;
2. Second crop season of confined field trials at the level of Biosafety Research Level I or Biosafety Research Level II.
3. Third crop season of confined field trials at the level of Biosafety Research Level II.

4 SCOPE

These guidelines are intended to provide guidance to applicants for the conduct of confined trials. They are not intended to explicitly define all the requirements for the conduct of a confined field trial, as further terms and conditions/requirements may be identified during the review process by the Regulatory Authorities.

This document covers all GE/transgenic plants modified through recombinant DNA (rDNA) technology.

5 TERMINOLOGY

5.1 Applicant

The Applicant must be a permanent resident of India or must designate an Authorized Signatory (AS) who is a permanent resident of India. Where an AS is used, there must be a formal, legal agreement indicating the AS is acting on behalf of the Applicant and both under the jurisdiction of any Court of Law of India. A copy of this agreement must be submitted to the Regulatory Authorities along with the confined field trial application. The Applicant need not be the breeder/developer or owner of the regulated plant, in which case a signed statement is required from the breeder/developer or owner authorizing representation by the Applicant or the designated AS. All correspondence with respect to the application for a confined field trial, including the notification of authorization, will be addressed to the Applicant, or when appropriate, the AS.

5.2 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. Applicants must use the proforma attached in Annexure 1.

5.3 Authorization

A letter of intent or permit issued by the Regulatory Authority (RCGM or GEAC) to conduct any research experiment on GE plants under specified terms and conditions.

5.4 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.

5.5 Confined Field Trial

A confined field trial is a field experiment of a regulated GE plant under terms and conditions that are intended to mitigate the establishment and spread of the plant. A single confined field trial may be comprised of one or more varieties/hybrids of a single event of a single plant species that are subject to the same terms and conditions of confinement which include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. The field trials are categorized into two types: Biosafety Research Level I and Biosafety Research Level II trials.

5.6 Construct

An engineered DNA fragment containing, but not limited to, the DNA sequences to be integrated into the genome of the target plant.

5.7 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.

5.8 Genetic Engineering

The technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material.

5.9 Government/ government agencies

Government means Central or State Government and Government Agencies that are associated organizations/ bodies with Central or State Government.

5.10 Monitoring agencies

Includes Monitoring cum Evaluation Committee (MEC) set up by RCGM as per the Guidelines for research in transgenic plants, 1998, pre release monitoring teams set up by the state agricultural universities (SAUs) under the directions of RCGM/ GEAC/SBCC/DLC or any other persons/organizations nominated by RCGM/ GEAC for monitoring of confined field trials.

5.11 Permitted Party

The Applicant or designated AS will be considered the 'Permitted Party' for the purposes of authorization and is the person who shall accept responsibility for compliance with the terms and conditions of the permit. The 'Permitted Party' may designate a Trial In-Charge, who will be responsible for ensuring compliance with the requirements of authorization as specified by the Regulatory Authority.

5.12 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.

5.13 Regulated Plant

Any plant produced through genetic engineering, including seed or propagable plant material derived from that plant, which has not been authorized by the Regulatory Authorities for commercial cultivation pursuant to the Rules, 1989 of the Environmental Protection Act, 1986.

5.14 Regulatory Authority

As regards confined field trials, RCGM is the Regulatory Authority responsible for authorizing Biosafety Research Level I trials and GEAC is the Regulatory Authority responsible for authorizing Biosafety Research Level II trials.

5.15 Seed

Seed means any type of embryo or propagule capable of regeneration and giving rise to a plant of agriculture which is true to such type. The definition of the seed will be taken as per the rules applicable at that point of time.

5.16 Site Map

Map of the trial site providing sufficient details on the dimensions, distances to physical landmarks, layout of the site etc. to allow regulatory officials/monitoring agencies to locate each field trial site during the planting season as well as during any required period of post harvest land use restriction.

5.17 Transformation

The process of incorporating DNA into an organism's genome. There are several methods to do this in plants. The most commonly used methods for plant transformation are *Agrobacterium*-mediated transformation and biolistic transformation.

5.18 Trial In-Charge

The technical person designated by the Permitted 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 Regulatory Authorities. The Trial In-Charge must, at a minimum, be an agriculture graduate.

5.19 Trial Protocol

The protocol for conducting a confined field trial approved by the Regulatory Authorities.

5.20 Trial Site

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

6 APPLICATIONS FOR CONFINED FIELD TRIALS

6.1 General Information for Submitting an Application

Biosafety Research Level I trials: The application form must be completed using the proforma provided in Annexure 1 and submitted by regular mail or courier delivery to:

Member Secretary, RCGM
Department of Biotechnology, Block 2, 8th Floor, CGO Complex, Lodhi Road, New Delhi -110003

Biosafety Research Level II trials: The application form must be completed using the proforma provided in Annexure 1 and submitted by regular mail or courier delivery to:

Member Secretary, GEAC
Ministry of Environment & Forests, Govt. of India
Paryavaran Bhawan, CGO Complex, Lodhi Road, New Delhi-110 003

All the applications must be duly recommended and forwarded by the IBSC. Copy of the IBSC minutes should be attached with the application.

If the regulated plant intended for use in a confined field trial has been imported, a copy of the Import Permit obtained from RCGM should be attached with the application and if the same has been taken from any other institutions within the country, a copy of the exchange permit obtained from RCGM should be attached with the application.

6.2 Application and Authorization/Approval Process

6.2.1 When to Apply

Applications for confined field trials must be received at least 60 days in advance of the proposed trials as per the trial season viz. Rabi or Kharif. RCGM/GEAC conducts an initial review, within 7 working days of receipt, and if the application is complete, it is included in the agenda and placed for review by RCGM/GEAC. If the application is not complete, the Applicant is advised as to the additional information required and will have to resubmit a new completed application that will include the additional information. The review process does not begin until a completed application has been received

6.2.2 Involvement of other Institutions

On a case-by-case basis, RCGM/GEAC may provide copies of the application to other government agencies, institutions or experts, for their comments and advice/review.

6.2.3 Authorization/approval process

Following the completed review, authorization of the confined field trial will be granted or denied. Where authorization is denied, the Applicant is informed of the reason(s) and provided with an appeal opportunity as per the provisions of Rules 1989.

The letter of authorization (permit letter) will generally contain the following elements:

1. 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.
2. A permit number to be used on all subsequent correspondence relating to the confined field trial.
3. 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.

6.3 Completing the Application Form

Applicants for a new confined field trial or a renewal must use the enclosed application form. The application form, including any enclosures, must be printed only on one side and additional material submitted to support the information requirements detailed in Parts F, G, or H, must be organized and numbered to correspond to the appropriate Part and sub-Part. Reprints of journal articles may be included with the application if they directly address an information requirement (*e.g.*, plasmid nucleotide sequence or genetic map). If the application cites any pre-prints of publications, these must be included in the application, and any enclosure attached that is not in the public domain and is proprietary may be claimed as confidential business information (see 6.4).

One application form may be used when testing one or more events of the same plant species as long as the different events exhibit the same phenotype. In such cases, a separate Part-F of the application must be submitted for each event. For example, in the case of insect-resistant events of the same plant species with the same phenotype (*e.g.*, resistance to cotton bollworm) produced by transformation with two different vector constructs (*e.g.*, different *cry* genes), two separate Part-F submissions must be included within the single application. However, where events express different phenotypes, two different applications are required. For

example, in the case of insect-resistant events of the same plant species with different phenotypes (*e.g.*, one event with resistance to cotton bollworm and one event with resistance to whitefly) two separate applications will be required even if the trials are being conducted at the same trial site location.

Similarly, when the intention is to conduct a confined field trial of the same plant species genetically engineered to express the same phenotypic trait (*e.g.*, resistance to tobacco streak virus) under the same conditions of reproductive isolation at more than a single trial site location, separate Part G and Part H submissions for each trial site must be included in the application.

In addition, the following considerations should be kept in mind when completing the information requirements:

6.3.1 Part-A: Application Type

Applications may be new or renewals and the same must be clearly identified on the application.

Renewals of authorization for confined field trials, including ongoing trials of perennial GE plants, may be granted for trials that are identical (*i.e.*, same species, construct, events and location) to those approved in previous years. Gene constructs, genetic modifications, plant material, trial purposes, experimental protocols, and the trial sites (including size and location) must be identical to those reviewed and authorized in previous years. Applications for renewals must be received at least sixty (60) days prior to the proposed planting date. The review of an application for renewal of a confined field trial will include a consideration of the Applicant's compliance history.

The terms and conditions of authorization required in previous years still apply, however, RCGM/GEAC reserves the right to modify, add, or remove any condition of authorization upon renewal. If granted, authorization for a renewal will be communicated in a letter of authorization (permit letter).

For renewals, the copy of the previous confined field trial permit must be included and the rest of the application must be completed in full and identical to the original application.

The application must also clearly identify if the subject trial(s) are Biosafety Research Level I or Biosafety Research Level II trials.

When an application is deemed incomplete and the Applicant is advised of the additional information required, a completed application must be resubmitted in its entirety. The previous incomplete application is considered as discarded and no records will be retained by the RCGM/GEAC Secretariat.

6.3.2 Part-B: Applicant and Part-C: Designated AS

As stated in 5.1 above, the Applicant must be a permanent resident of India, or must designate an Indian Authorised Signatory (AS). For foreign applicants, both Part-B and Part-C must be completed. For Indian applicants, completion of Part-C is not required.

6.3.3 Part-D: Applicant/AS Verification

All correspondence with respect to the application, including the notification of authorization/permit, will be addressed to the Applicant, if a resident of India, or the designated AS, if the Applicant is a non-resident. In the event of authorization, this person shall be the Permitted Party (see 5.11 above) for the purposes of conduct of the confined field trial. The Permitted 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. However, as per the agreement between the Applicant and the AS, both are under the jurisdiction of Indian Laws.

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 RCGM/GEAC prior to the granting of an authorization/approval for a confined field trial.

6.3.4 Part-E: 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.

RCGM/GEAC will be publishing Biology Documents for some plant species commonly tested in India. Where these are available, they should be consulted to complete the information requirements of Part-E (1-14).

If a Biology Document for a plant species has not been published by RCGM/GEAC, the Applicant is required to submit one for review, along with the completed application for a confined field trial. The Member Secretary, RCGM/GEAC may be consulted for further information on the content and format requirements, and the review procedures for Biology Documents.

6.3.5 Part-F: Information on the Genetically Engineered Plant

Sufficient information about the regulated, GE 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 genetically engineered plant. If there is any likelihood that introduced genetic material may be mobilized out of the genetically engineered 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 Regulatory Authorities 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 draught tolerance, nutritional enhancement etc.) this must be described.

6.3.6 Part-G: 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 India.

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 taluk. 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 Member Secretary, RCGM/GEAC preferably 7 working days before sowing/planting and positively within 7 working days after sowing/planting of the trial site (see 6.5).

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.

6.3.7 Part-H: 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 RCGM/GEAC 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 RCGM/GEAC. 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 RCGM/GEAC in the permit letter.

6.4 Confidential Business Information

In situations where the application will entail the disclosure of confidential business information (CBI) or proprietary information, a complete application must still be submitted. Insufficient information will hinder the review process. RCGM/GEAC will not disclose CBI to any unauthorized person, as per the provisions of existing laws of the country.

For information claimed as CBI, the Applicant must provide a written justification. Published literature usually cannot be claimed as CBI.

In an application where CBI will be disclosed the entire application cannot be considered CBI. The Applicant must indicate the parts of the application that contain CBI by clearly marking the term “CBI” 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 where CBI material is presented.

Applicants should bear in mind that RCGM/GEAC may provide copies of the application to other government agencies, institutions for their review or any person/agency seeking information under Right to Information Act 2005 (RTI).

6.5 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 RCGM/GEAC preferably no later than 7 days before sowing/planting and positively within 7 working days after sowing/planting at the trial site. In the event this latter requirement is not met, RCGM/GEAC reserves the right to cancel the authorization and require termination of the confined field trial. The provision of draft maps at the time of application is recommended as this will facilitate the assessment of conduct of trials.

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.

A map of the trial site will be prepared by the Trial In-Charge and appended to the Record of Planting (see the RCGM/GEAC Standard Operating Procedures for the Management of Confined Field Trials).

Maps must provide sufficient detail to allow regulatory officials/monitoring agencies to locate each field trial site during the planting season and any required period of post-harvest land use restriction.

Maps must provide details on the layout of the site and distances between the field trial site and surrounding features like names of the land owners/farmers, any specific marks/features etc.

The dimensions of the trial site and distances to physical landmarks must be accurately reported.

The following items shall be included on each map of a field trial site:

1. Trial In-Charge's name and contact details.
2. Permit number from the Regulatory Authority.
3. Legal or descriptive land location (name of the village, taluka, district, state.)
4. Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.
5. Total area planted with the regulated material, including negative controls and any border or guard rows when used (hectares or square meters).
6. Label all fields within the isolation area by the common name of the crop.
7. Indicate any fields of same/related crops that fall within, or border on, the isolation area.
8. Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, garden, orchard, forests, and woodlots, hedgerows), wherever reasonable.
9. Planting date.
10. Compass directions, with North at the top of the page.

A signboard at the site with the above information must be erected until after the period of post-harvest land use restriction has been completed.

7 GENERAL REQUIREMENTS FOR CONFINED FIELD TRIALS

It is solely the responsibility of the Permitted Party to ensure compliance with all of the terms and conditions of authorization of a confined field trial. This responsibility extends to cover the actions of any subcontractors, cooperators or any agencies/persons/farmers that may work on the trial site or otherwise handle the subject GE plant material. The onus is on the Permitted Party to ensure that the confined field trial will comply with all conditions without breach.

7.1 Restrictions on the Size and Number of Confined Field Trial Sites

Confined field trials of GE plants for research purposes 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. The confined field trial system is not intended to support other activities, such as commercial seed multiplication or the cultivation of regulated GE plant material for direct export from India.

In order to maintain the integrity of this system, confined field trials are subject to restriction in size and number, unless the Applicant applies for an exemption to one or both of the following:

Biosafety Research Level I trials are limited in size to no more than 1 acre (0.4 ha) per trial site location and a cumulative total of 20 acres (8.1 ha) for all locations for each plant species/construct combination (*e.g.*, one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.

Biosafety Research Level II trials are limited in size to no more than 2.5 acres (1 ha) per trial site location and to no more than eight (8) locations within India for each plant species/construct combination (*e.g.*, one or more events originating from transformation of a plant species with the same genetic construct), per Applicant, per crop season.

Exemptions from these restrictions on trial size and the number of site locations may be granted in cases where a valid scientific research rationale may be considered by the Regulatory Authorities. This rationale must be provided in the application.

7.2 Monitoring of Confined Field Trials

Members of the MEC, SBCCs, DLCs and monitoring teams of SAUs have the authority to inspect confined field trial sites at the time of planting, during the growing and harvesting season, and the period of post-harvest land

use restriction for compliance with the terms and conditions of authorization. Monitoring agencies also have the authority to inspect contained facilities that may be used for the storage of regulated genetically engineered plant material. The Trial In-Charge, or Facility-in-Charge (for storage facilities) as appropriate, may accompany the monitoring teams on inspections; however, the coordination of such activities is the responsibility of the Permitted Party.

7.3 Records and Reporting

7.3.1 Compliance Records

Records of all confined field trials, including pre- 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, shall be maintained by the Permitted Party and shall be made available to RCGM/GEAC or the designated monitoring agencies upon request.

Mandatory recording formats are referenced in the RCGM/GEAC Standard Operating Procedures (SOPs) for Confined Field Trials of Genetically Engineered Cotton: Transport, Storage, Management, Harvest or Termination and Post Harvest Management and can be downloaded from http://igmoris.nic.in/.

7.3.2 Field Trial Report

The Permitted Party shall submit a field trial report to RCGM/GEAC within 3 months after termination/ harvest of a confined field trial. The field trial report must summarize the completed trial, including methods, observations, data and analysis of any effects of the trial plants on other plants, non-target organisms, or the environment.

7.3.3 Mandatory Information Submissions by Applicant

Planting Information Submission: RCGM/GEAC 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 (see section 6.5).

Harvest Information Submission: 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 verified and signed by a member of the Monitoring Agency or any nominee of RCGM/GEAC/SBCC/DLC/SAU authorized by RCGM/GEAC during the conduct of a trial site inspection during harvest, or within 15 days of the completion of harvest.

Accidental Release Information: The Permitted Party shall notify RCGM/GEAC immediately upon discovery by telephone but positively within 24 hours in writing (submission to be received by RCGM/GEAC within 24 hours by facsimile, e-mail or other means) of any incident involving an accidental or unauthorized escape like spillage, theft, encroachment by unauthorized persons, vandalization etc. of regulated GE plant material during transportation, storage within a contained facility, or during any other activity associated with the conduct of a confined field trial. For the purposes of these Guidelines, any breach of the authorized terms and conditions of reproductive isolation shall be considered an accidental release and subject to risk assessment and management if any at the cost of the applicant or Permitted Party.

Other Submissions : In the event that the plants undergoing confined field trial testing exhibit any characteristics substantially different from those known for the host plant species, or anticipated and listed in the application, or suffers any unusual occurrence, the Permitted Party shall notify RCGM/GEAC in writing within five (5) days of such observations.

7.4 Reproductive Isolation of Confined Field Trials

A confined field trial is a field experiment of a regulated GE plant under terms and conditions that are intended to mitigate the establishment and spread of the plant.

To prevent their establishment and spread within the environment, regulated GE plants within a confined trial must be reproductively isolated from sexually compatible plant species in proximity to the trial site, and any progeny plants that arise on the trial site after completion of the trial must be eliminated.

It is the responsibility of the Permitted 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.

7.4.1 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.

The spatial isolation area defined by the isolation distance must be continuous and completely surround the confined trial site. Any prohibited plants found growing within the isolation area 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 isolation area.

Minimum isolation distances and periods of post-harvest land use restriction for various plant species will be established by RCGM/GEAC on case-by-case basis. RCGM/GEAC reserves the right to change the minimum spatial isolation distance for specific applications, depending upon the type of crop, the event and any other circumstances where this is deemed necessary.

7.4.2 Alternative Methods of Reproductive Isolation

Other methods that may be acceptable to reproductively isolate regulated GE plants are provided below. Applicants should refer to the crop-specific RCGM/GEAC SOPs to determined if alternative methods of reproductive isolation will be permitted:

1. Removal of floral parts before pollen maturity.
2. Bagging of flowers/tassels to prevent open pollination.
3. Termination of the trial prior to flowering.
4. Temporal isolation of pollination (*i.e.*, planting earlier or later than any nearby sexually compatible plants so that flowering is asynchronous).
5. Planting of border rows of non-regulated plants of similar variety as the trial plants to act as a pollen trap. This is only applicable to insect-pollinated crops and only when experimental studies have demonstrated that pollen traps are as effective as spatial isolation for the purpose of reproductively isolating a field trial site.

When border rows are authorized as an alternative means of reproductive isolation, the Permitted Party shall ensure that the plants in the border rows 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 trap row plants have completed this stage, a breach of border row isolation will have occurred. All plants within the border row area must be disposed of in the same manner as the regulated trial plants. The border row area will be subject to the same conditions of post-harvest land use restriction and monitoring as the trial site proper.

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.*, border row failure because the trial plants flowered before the border row plants), the reproductive isolation method may revert to the spatial isolation distance where this can be effectively implemented. For this reason, the Permitted Party is strongly encouraged to

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.

7.5 Disposition of Material from Confined Field Trials

No harvested material or byproduct from a confined field trial may be used as human food or livestock feed. Seed or other plant material harvested from confined trials (including border rows) that has not been previously authorized by RCGM/GEAC to be retained for future research work, must be disposed of by a method approved by RCGM/GEAC (*e.g.*, dry heat, steam heat, incineration, deep burial, chemical treatment, or crushing or burying on the trial site). Composting is not an acceptable method for the disposal of plant material especially in open pit with any organic animal waste.

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

7.6 Post-Harvest Land Use Restrictions and Post-Harvest Monitoring

In addition to ensuring reproductive isolation of the field trial site 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, RCGM/GEAC would establish a post-harvest period for various plant species on a case-by-case basis and requires that the following precautions be implemented during this period:

1. The area under restriction must be monitored during the post-harvest period to ensure that any prohibited plants (volunteers or sexually compatible species) are destroyed prior to flowering.
2. No plants of the same or a sexually compatible species may be planted in the restricted area during the post-harvest period.
3. 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, including the border row area if border rows were used as an alternative method of reproductive isolation, and does not include the surrounding isolation area. 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 isolation area.

7.7 Standard Terms and Conditions of Authorization

The following terms and conditions shall apply to all confined field trials and shall be appended to each letter of permit:

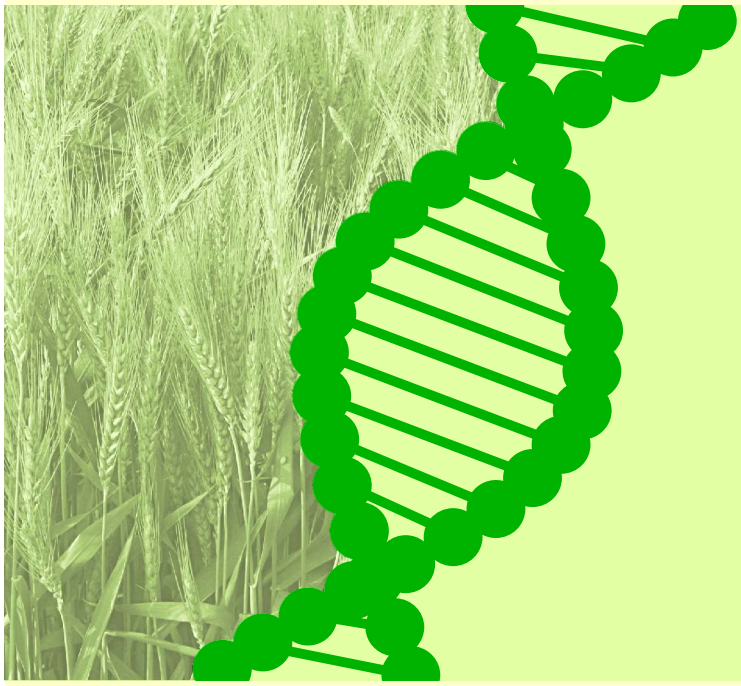
1. The Permitted Party shall ensure that genetically engineered seed and/or plant material for planting is transported in clearly identified, secure containers and kept separate from other seed and/or plant material. All packing material, shipping containers, and any other material accompanying the genetically engineered plant material shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of this material or any progeny plants.
2. In the case of accidental release or spillage of genetically engineered plant material during transport, recoverable seeds or seedlings shall be collected and rendered non-viable and disposed of, the site shall be marked and monitored, and a notification shall be immediately provided to RCGM/GEAC. Any plants arising from unrecoverable seed or seedlings must be rendered non-viable and disposed of before flowering.
3. Any equipment or tools 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 rendered non-viable and disposed of using a method acceptable to RCGM/GEAC such as: dry heat, steam heat, incineration, crushing, deep burial to one metre on the trial site, or chemical treatment.

4. The Permitted Party or Trial In-Charge must mount a Notice Board at the trial site indicating the purpose and duration of the confined field trials conducted at the trial site and the authority under which the confined field trials were approved.
5. Planting information shall be submitted to RCGM/GEAC within 7 working days following the completion of planting at a trial site. This notification must also include a detailed map of the trial site if it was not provided with the original application.
6. The Permitted Party shall maintain adequate records of all confined field trials, including pre- 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.
7. No seed or other plant material from the confined field trial may enter the human food or animal feed chains.
8. Harvested seed and/or plant material from the confined trial may only be retained if requested in the application and previously authorized by RCGM/GEAC. Any harvested seed and/or plant material must be clearly labelled, securely transported, and stored separately from other seed and/or plant material.
9. A record of harvest 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 Permitted Party for verification and signature by monitoring agency. This harvest inspection shall occur either during harvest or within 15 days of the completion of harvest.
10. The Permitted Party shall notify RCGM/GEAC in writing at least 15 days in advance of planting any plant species on the trial site during the post-harvest period.
11. The Permitted 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 RCGM/GEAC within 3 months after the termination of the confined field trial.
12. Monitoring agencies shall be allowed access, during regular business hours, to the place where regulated genetically engineered plant material is located and to any records relating to the transportation, storage, or use of the genetically engineered plant material in a confined field trial.
13. If a chemical treatment is used on the trial site that requires a time until safe 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 entry. This condition is intended to protect the health and safety of monitoring agencies.
14. RCGM/GEAC shall be informed within the time periods and manner specified below, in the event of the following occurrences:

    a. In the event of any accidental or unauthorized escape of genetically engineered plant material, the Permitted Party must notify RCGM/GEAC immediately upon discovery in writing but positively within 24 hours.

    b. If the genetically engineered plant under trial is found to have characteristics substantially different from those listed in the application or suffers any unusual occurrence, in writing as soon as possible but not later than within five days

Supplementary terms and conditions of authorization specific to the genetically engineered plant species and/or the trial site will also be included in the letter of permit from RCGM/GEAC.



APPLICATION FOR CONFINED FIELD TRIAL

APPLICATION FOR CONFINED FIELD TRIAL

INSTRUCTIONS:

- ❒ This application form must be completed for each plant species. The application may include more than one event of the same plant species as long as the trait phenotype is the same for each event. A separate Part F of this application must be completed for each event, a separate Part G must be completed for each trial site and a separate Part H must be completed for each trial protocol.

- ❒ 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.

- ❒ 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. Those parts of the application that are considered to be CBI must be indicated as such. The entire application may not be considered as CBI.

- ❒ Applications must be received by the RCGM/GEAC Member Secretary, at the address shown below at least 60 days in advance of any proposed trial.

Member Secretary, RCGM
Department of Biotechnology
Ministry of Science & Technology
Block-II, CGO Complex
Lodhi Road
New Delhi – 110 003

Member Secretary, GEAC
Ministry of Environment & Forest
Paryavaran Bhawan, CGO Complex
Lodhi Road
New Delhi - 110 003

PLEASE PRINT CLEARLY

PART A. APPLICATION TYPE ("✓" one)

☐ new ☐ renewal

☐ Event selection trial ☐ Biosafety Research Level I trial ☐ Biosafety Research Level II trial

PART B. APPLICANT

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

Date application received	_____
Date initial review completed	_____
Application complete?	☐ yes ☐ no
Non-CBI application submitted for external review?	☐ yes ☐ no
If YES, indicate external reviewer	_____
Final determination	☐ authorized ☐ denied
Effective date of authorization	_____
Field authorization code	_____

Signature of Regulatory Official _____ Date signed _____

PART C. AUTHORISED SIGNATORY

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

Has this application received IBSC recommendation? ☐ yes ☐ no

If **YES**, please attach a copy of the IBSC minutes where this application was recommended.

If **NO**, this application will not be accepted by RCGM/GEAC until IBSC recommendation has been obtained.

PART D. APPLICANT / AGENT VERIFICATION

This application is submitted in accordance with requirements specified in GUIDELINES FOR CONDUCT OF CONFINED FIELD TRIALS OF REGULATED GENETICALLY ENGINEERED PLANTS IN INDIA.

Signature of Applicant and/or Authorised Signatory, as appropriate

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 authorization, including all legal and financial responsibility associated with any compliance infractions.

Date signed

(DD-MM-YYYY)

PART E. UNMODIFIED PLANT SPECIES

E.1 Latin name _____ E.2 Common name _____

E.3 Biology document for the plant species is ☐ attached ☐ published by regulatory agency

E.4 Is the plant species considered to be weedy or naturally invasive? ☐ yes ☐ no

If YES, list any locations below.

_____

E.5 Are there significant free-living[1] populations of the plant species in India? ☐ yes ☐ no

If YES, list any locations below.

_____

E.6 Are there sexually compatible wild relatives of the plant species in India? ☐ yes ☐ no

If YES, list any locations below.

_____

E.7 Known centre(s) of origin of plant species

_____

E.8 Known centre(s) of genetic diversity

_____

E.9 Main mechanism of pollen dispersal: ☐ wind borne ☐ insects (list species)

_____

E.10 Mechanisms of natural seed dispersal: ☐ none ☐ birds ☐ wind ☐ other wildlife

Other details, below.

_____

E.11 Seed dormancy (including tubers) ☐ <=1 YR ☐ <=2 YR ☐ <=3 YR

Other, below.

_____

[1] The term 'free-living' is assigned to plant populations that are able to survive, without direct human assistance, over the long term in competition with the native flora.

PART E. UNMODIFIED PLANT SPECIES (cont'd)

E.12 Is the plant species known to be allelopathic? ☐ yes ☐ no

E.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.

_____

E.14 Is the plant species known to be a source of human allergens? ☐ yes ☐ no

If YES, identify the allergenic proteins.

_____

PART F. INFORMATION ON THE GENETICALLY ENGINEERED PLANT

F.1 NAME OR DESIGNATION OF EVENT(S)

Enter the identification code or event name for each transgenic event included in the plant genotype.

_____

F.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
☐ OO - other _____

F.3 IMPORTATION OF PLANT MATERIAL

F.3-1 Was any plant material for use in the confined field trial imported? ☐ yes ☐ no

F.3-2 Import permit number _____

F.3-3 Date of import _____

F.4 PHENOTYPE

Enter a short phrase describing the plant phenotype (*e.g.* , resistance to lepidopteron insects).

_____

PART F. INFORMATION ON THE GENETICALLY ENGINEERED PLANT (cont'd)

F.5 PREVIOUS CONFINED FIELD TRIALS

F.5-1 Event(s) previously tested in India? ☐ yes ☐ no

If YES, enter most recent trial authorization code. _____

F.5-2 Event(s) previously tested in other countries? ☐ yes ☐ no

If YES, list countries and year of approval.

_____

F.6 MODIFICATION METHOD

☐ AT - agrobacterium mediated transformation ☐ PF - protoplast fusion ☐ BT - biolistic/particle gun transformation
☐ OO - other _____

F.7 PREVIOUS APPROVAL FOR UNCONFINED RELEASE

F.7-1 Event(s) previously approved for unconfined (general or commercial) release in other countries? ☐ yes ☐ no

If YES, list countries and year of approval.

_____

F.8 SELECTION METHOD USED IN PLANT REGENERATION

☐ AP - antibiotic resistant ☐ HT - herbicide tolerant ☐ SU - substrate utilization
☐ OO - other _____

F.9 INTRODUCED DNA

☐ PL - intact plasmid ☐ RF - DNA fragment

F.9-1 Plasmid name _____

F.9-2 Plasmid and/or construct map attached? ☐ yes ☐ no

F.9-3 Does the introduced DNA give rise to any infectious agents? ☐ yes ☐ no

If you answered YES, provide details.

_____

_____

PART F.9 INFORMATION ON THE GENETICALLY ENGINEERED PLANT - Introduced DNA (cont'd)

F.9-4 Does the introduced DNA contain any sequences derived from known human or animal pathogens? ☐ yes ☐ no

If you answered YES, provide details.

F.9-5 Briefly describe the derivation of the transformation vector or transforming DNA.

F.9-6 If you answered YES to F.9-3 or F.9-4, provide further details below.

F.10 DATA SHEET FOR RECORDING CONSTRUCT COMPOSITION

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.

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other _____

Starting Pos (bp) _____ **Name** _____

Ending Pos (bp) _____ **Donor organism** _____

Size (kb) _____ **Species name** _____

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other _____

PART F.10 INFORMATION ON THE GENETICALLY ENGINEERED PLANT - Data Sheet for Recording Construction Composition (cont'd)

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other ______

Starting Pos (bp) ______ **Name** ______

Ending Pos (bp) ______ **Donor organism** ______

Size (kb) ______ **Species name** ______

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other ______

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other ______

Starting Pos (bp) ______ **Name** ______

Ending Pos (bp) ______ **Donor organism** ______

Size (kb) ______ **Species name** ______

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other ______

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other ______

Starting Pos (bp) ______ **Name** ______

Ending Pos (bp) ______ **Donor organism** ______

Size (kb) ______ **Species name** ______

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other ______

PART F.10 INFORMATION ON THE GENETICALLY ENGINEERED PLANT - Data Sheet for Recording Construction Composition (cont'd)

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other _____

Starting Pos (bp) _____ **Name** _____

Ending Pos (bp) _____ **Donor organism** _____

Size (kb) _____ **Species name** _____

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other _____

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other _____

Starting Pos (bp) _____ **Name** _____

Ending Pos (bp) _____ **Donor organism** _____

Size (kb) _____ **Species name** _____

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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** ☐ OO - other _____

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other _____

Starting Pos (bp) _____ **Name** _____

Ending Pos (bp) _____ **Donor organism** _____

Size (kb) _____ **Species name** _____

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other _____

PART F.10 INFORMATION ON THE GENETICALLY ENGINEERED PLANT - Data Sheet for Recording Construction Composition (cont'd)

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other ______

Starting Pos (bp) ______ **Name** ______

Ending Pos (bp) ______ **Donor organism** ______

Size (kb) ______ **Species name** ______

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other ______

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other ______

Starting Pos (bp) ______ **Name** ______

Ending Pos (bp) ______ **Donor organism** ______

Size (kb) ______ **Species name** ______

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other ______

Feature type ☐ CD - coding ☐ AS - antisense ☐ EH - ehancer ☐ PR - promoter ☐ TR - termination/polyadenylation ☐ SS - signal sequence ☐ OO - other ______

Starting Pos (bp) ______ **Name** ______

Ending Pos (bp) ______ **Donor organism** ______

Size (kb) ______ **Species name** ______

Donor organism source of toxins or allergens? ☐ yes ☐ no **Protein expressed** ☐ yes ☐ no

Trait category ☐ 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 ☐ OO - other ______

PART F. INFORMATION ON THE GENETICALLY ENGINEERED PLANT (cont'd)

F.11 DATA SHEET FOR RECORDING EXPRESSION PRODUCTS OF INTRODUCED GENE(S)

Provide information for each protein product of the introduced DNA.

Name of protein _____

Indicate if expression of the protein is ☐ CS - constitutive ☐ TS - tissue specific ☐ IN - inducible ☐ DS - development specific
If expression is NOT constitutive, list specific tissues, inducers, or development phase of maximal expression _____

Maximum level of expression in the edible portions of the plant, <u>if known</u> (µg/g) _____

Is the protein a known human allergen? ☐ yes ☐ no

If YES, provide details.

_____

_____

Is the protein known to be toxic to humans or non-target organisms? ☐ yes ☐ no

If YES, provide details.

_____

_____

Name of protein _____

Indicate if expression of the protein is ☐ CS - constitutive ☐ TS - tissue specific ☐ IN - inducible ☐ DS - development specific
If expression is NOT constitutive, list specific tissues, inducers, or development phase of maximal expression _____

Maximum level of expression in the edible portions of the plant, <u>if known</u> (µg/g) _____

Is the protein a known human allergen? ☐ yes ☐ no

If YES, provide details.

_____

_____

Is the protein known to be toxic to humans or non-target organisms? ☐ yes ☐ no

If YES, provide details.

_____

_____

Name of protein _____

Indicate if expression of the protein is ☐ CS - constitutive ☐ TS - tissue specific ☐ IN - inducible ☐ DS - development specific
If expression is NOT constitutive, list specific tissues, inducers, or development phase of maximal expression _____

Maximum level of expression in the edible portions of the plant, <u>if known</u> (µg/g) _____

Is the protein a known human allergen? ☐ yes ☐ no

If YES, provide details.

_____

_____

Is the protein known to be toxic to humans or non-target organisms? ☐ yes ☐ no

If YES, provide details.

_____

_____

PART F. INFORMATION ON THE GENETICALLY ENGINEERED PLANT - Data Sheet for Recording Expression of Products of Introduced Gene(s) (cont'd)

Name of protein _____

Indicate if expression of the protein is ☐ CS - constitutive ☐ TS - tissue specific ☐ IN - inducible ☐ DS - development specific

If expression is NOT constitutive, list specific tissues, inducers, or development phase of maximal expression _____

Maximum level of expression in the edible portions of the plant, <u>if known</u> (µg/g) _____

Is the protein a known human allergen? ☐ yes ☐ no

If YES, provide details.

Is the protein known to be toxic to humans or non-target organisms? ☐ yes ☐ no

If YES, provide details.

Name of protein _____

Indicate if expression of the protein is ☐ CS - constitutive ☐ TS - tissue specific ☐ IN - inducible ☐ DS - development specific

If expression is NOT constitutive, list specific tissues, inducers, or development phase of maximal expression _____

Maximum level of expression in the edible portions of the plant, <u>if known</u> (µg/g) _____

Is the protein a known human allergen? ☐ yes ☐ no

If YES, provide details.

Is the protein known to be toxic to humans or non-target organisms? ☐ yes ☐ no

If YES, provide details.

F.12 INTENDED OR ANTICIPATED CHANGES TO PLANT CHARACTERISTICS

F.12-1 Is the genetic modification intended to alter plant weediness? ☐ yes ☐ no

If YES, describe.

F.12-2 Is the genetic modification intended to alter plant allelopathic characteristics? ☐ yes ☐ no

If YES, describe.

PART F.13 INFORMATION ON THE GENETICALLY ENGINEERED PLANT - Intended or Anticipated Changes to Plant Characteristics (cont'd)

F.12-3 Is the genetic modification intended to alter seed dormancy, viability, or germination rate? ☐ yes ☐ no

If YES, describe.

_____

F.12-4 Is the genetic modification intended to alter pollen dispersal? ☐ yes ☐ no

If YES, describe.

_____

F.12-5 Is the genetic modification intended to alter seed dispersal? ☐ yes ☐ no

If YES, describe.

_____

F.12-6 Is the genetic modification intended to alter vegetative dispersal? ☐ yes ☐ no

If YES, describe.

_____

PART G. INFORMATION ON THE TRIAL SITE

G.1 TRIAL IN CHARGE

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

PART G. INFORMATION ON THE TRIAL SITE (cont'd)

G.2 TRIAL SITE

Applicant's site location code _____

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

Legal or descriptive land location _____

Ownership and agreement details _____

Distance to nearest cultivated crop of the same species (m) _____

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

Is the isolation distance under the Trial-in Charge's control? ☐ yes ☐ no

G.3 TRIAL SITE MAP

G.3-1 Has a completed map of the trial site been enclosed? ☐ yes ☐ no

If not provided with the application, the completed map must be provided to RCGM/GEAC within seven (7) working days following sowing/planting.

G.3-2 Have you attached the experimental design of the trial? ☐ yes ☐ no

G.4 HABITAT

G.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?

_____

G.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.

_____

G.5 INDIGENOUS SPECIES

G.5-1 Describe any sexually compatible wild or cultivated plant species that are in the vicinity of the trial site.

_____

PART G INFORMATION ON THE TRIAL SITE - Indigenous Species (cont'd)

G.5-2 Are there any endangered or threatened species on or near the trial site? ☐ yes ☐ no

If YES, list them.

_____

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

_____

G.6 POST-HARVEST LAND USE

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

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

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

_____

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

_____

_____

PART H. THE TRIAL PROTOCOL

H.1 TRIAL PROTOCOL (STUDY) TITLE _____

H.2 DATES

H.2-1 Anticipated planting date _____

H.2-2 Anticipated harvest date _____

H.3 STUDY DESCRIPTION

H.3-1 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/pesticide use.

_____

_____

_____

_____

H.4 REPRODUCTIVE ISOLATION

H.4-1 Check one or more as appropriate.

☐ spatial isolation distance ☐ detasseling/removal of floral parts ☐ guard rows ☐ bagging
☐ temporal isolation ☐ trial terminaton before flowering

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

_____

_____

H.5 TRANSPORTATION

H.5-1 Describe how genetically engineered seed and/or plant material will be packaged for transport.

_____

_____

PART H.5 THE TRIAL PROTOCOL - Transportation (cont'd)

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

H.5-3 Describe how containers or packets containing genetically engineered seed or plant material will be labelled.

H.5-4 Describe how chain of custody will be ensured and the type of records that will be retained.

H.6 PLANTING

H.6-1 How will material be planted? ☐ by hand ☐ mechanically

H.6-2 Will any unmodified plants of the same or a related species be planted at the trial site location? ☐ yes ☐ no

H.6-3 If you answered YES to H.6-2, briefly explain why.

H.6-4 If any equipment is to be used during planting, explain how it will be cleaned on the trial site.

PART H.6 THE TRIAL PROTOCOL - Planting (cont'd)

H.6-5 Describe how surplus planting material will be rendered ***nonviable*** at the trial site.

H.6-6 Describe how quantities of seed planted and any excess will be recorded.

H.7 PESTICIDE APPLICATIONS

Complete this section only if an unregistered product will be used at the trial site.

H.7-1 Name of the unregistered pesticide

H.7-2 Number of applications per season

H.7-3 Active ingredient

H.7-2 Total area to be sprayed (square meters)

H.8 HARVESTING

H.8-1 Will plants be allowed to set seed? ☐ yes ☐ no

H.8-2 How will material be harvested? ☐ by hand ☐ mechanically

H.8-3 Will any harvested plant material be retained from the trial? ☐ yes ☐ no

H.8-4
If you answered YES to H.8-3, briefly explain the purpose of retaining plant material.

PART H.8 THE TRIAL PROTOCOL - Harvesting (cont'd)

H.8-5 If any equipment is to be used during harvesting, explain how it will be cleaned on the trial site.

_____

_____

H.8-6 Provide the name and address of the person responsible for the disposition and/or storage of harvested material, if it is NOT the Trial-in-Charge.

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

H.8-7 Describe the storage method and storage location of harvested materials, if applicable.

_____

_____

H.9 MONITORING THE TRIAL SITE

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

_____

_____

H.9-2 Describe what monitoring results will be recorded.

_____

_____

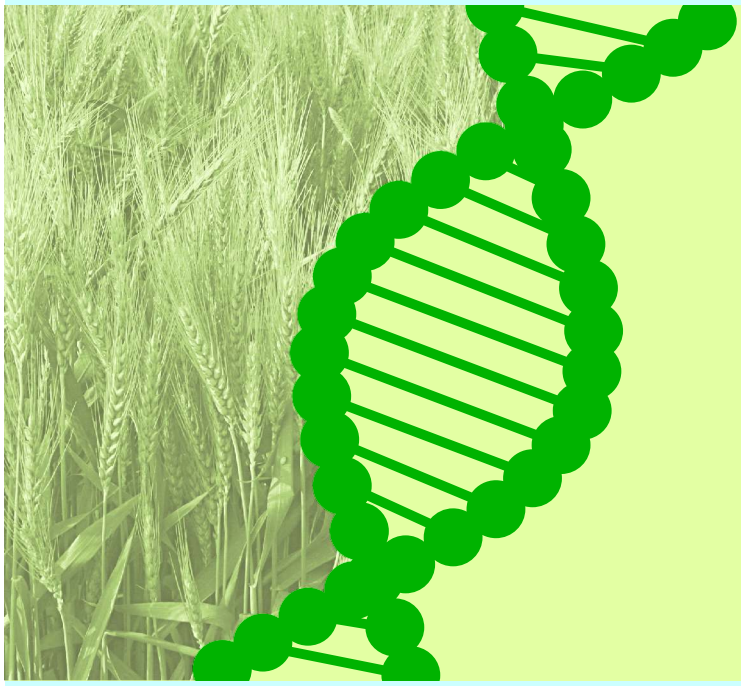
PART H.9 THE TRIAL PROTOCOL - Monitoring the Trial Site (cont'd)

H.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.

H.10 EMERGENCY PLANS FOR ACCIDENTAL RELEASE

H.10-1 Describe your contingency plans in the event of an accidental release of seed or plant material or a breach of reproductive isolation.

H.10-2 Describe your contingency plan in the event of an unexpected spread of genetically engineered plant material after an accidental release.



STANDARD OPERATING PROCEDURES (SOPs) FOR CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

STANDARD OPERATING PROCEDURES (SOPs) FOR CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

1. OBJECTIVE

Standard Operating Procedures (SOPs) have been prepared to provide guidance for the following aspects of conducting confined field trials of regulated, genetically engineered crops in India:

1. Transport of regulated GE plant material.
2. Storage of regulated GE plant material.
3. Management of confined field trials.
4. Management of harvest or termination of confined field trials.
5. Post-harvest management of confined field trials.

2. GENERAL REQUIREMENTS

2.1. The Permitted Party and all other agents acting on behalf of the Permitted Party must comply with these SOPs.

2.2. No regulated plant material from the trial site, including material from border rows when used, is permitted to enter the food or feed chains.

2.3. All the relevant Records are to be filled as per the requirements indicated in each SOP. The following formats of records have been enclosed.

i. Record of Transport & Transport Inventory List

ii. Record of Storage

iii. Record of Storage Inspection & Inventory

iv. Record of Planting

v. Record of Spatial Isolation

vi. Record of Harvest/Termination

vii. Record of Post-Harvest Monitoring

viii. Record of Corrective Action

2.4. In situations where it becomes known that there has been non compliance with the terms and conditions of the confined field trial permit due to any reasons, the Permitted Party must inform RCGM/GEAC immediately by telephone and positively within 24 hours in writing. RCGM/GEAC will provide the Permitted Party with the appropriate course of remedial action. The corrective actions should be appropriately recorded as explained in the subsequent sections.

3. TERMINOLOGY

The following terminology has been used in the SOPs

i. **Accidental release:** Any unintended release of regulated plant material into the environment, food and/or feed chains.

ii. **DBT**: Department of Biotechnology.

iii. **DLC**: District Level Committee.

iv. **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.

v. **Facility In-Charge**: For the purpose of this SOP, shall be the person designated by the Permitted Party as responsible for the storage of the regulated material.

vi. **Field trial:** The planting of one or more regulated events in a single experimental plot.

vii. **GEAC:** Genetic Engineering Approval Committee.

viii. **Genetic engineering:** The technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material (*Rules, 1989*).

ix. **IBSC:** Institutional Biosafety Committee.

x. **Isolation distance**: A spatial separation of the trial site from the nearest plant of the same or related species. Isolation distances are crop specific.

xi. **MEC:** Monitoring cum Evaluation Committee.

xii. **Methods of reproductive isolation:** Means used to prevent movement or dissemination of regulated plant material by pollen or seed from the confined trial site (*e.g.*, establishing an area around the perimeter of a trial site that is kept free of any prohibited plants for the period of the trial; terminating a confined field trial before the plants in the trial flower and release pollen).

xiii. **Packaging Material:** The material used to secure regulated, genetically engineered seed or other propagable plant material for the purposes of transport and storage. Examples include polythene bags, seed envelope, cardboard box.

xiv. **Permitted Party:** The sponsoring organization identified on a field trial permit issued by RCGM or GEAC who shall accept full responsibility for compliance with all terms and conditions of the permit.

xv. **Physical landmarks:** Landmarks used to identify or designate boundaries of a confined field trial site (*e.g.*, telephone poles, fences, alleys or roads).

xvi. **Plant material:** Propagable material (*e.g.*, seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagable material (*e.g.*, leaves, tissue samples).

xvii. **Post-harvest period**: A period of time that follows the harvest or termination of a confined field trial when restrictions are imposed on the use of the trial site.

xviii. **Primary container**: The container into which regulated plant material is placed (*e.g.* sealed bag, envelope, polythene bags, cardboard box etc).

xix. **Prohibited plants:** With reference to a confined field trial of a regulated, genetically engineered plant, prohibited plants include volunteers of the trial species and any other plant species that are sexually compatible with the trial species under field conditions.

xx. **Propagable:** Any plant or plant part that can be used to regenerate a whole plant under typical field conditions.

xxi. **Recipient**: For the purpose of this SOP, shall be the Permitted Party, Trial In-Charge or Facility In-Charge.

xxii. **RCGM:** Review Committee on Genetic Manipulation.

xxiii. **Regulated plant:** Any plant produced through genetic engineering, including seed or propagable plant material derived from that plant, which has not been authorized by the Government of India for commercial cultivation pursuant to *Rules, 1989*.

xxiv. **Rules, 1989**: Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells Rules, 1989 conferred by sections 6, 8 and 25 of the Environmental (Protection) Action, 1986.

xxv. **SBCC:** State Biotechnology Coordination Committee.

xxvi. **SAU:** State Agricultural University.

xxvii. **Secondary container**: The container into which a primary container is placed.

xxviii. **Transport In-Charge**: The person identified by the Permitted Party as being responsible for the transport of regulated plant material.

xxix. **Trial In-Charge:** The person/scientist designated by the Permitted Party as responsible for ensuring compliance with the terms and conditions of a confined field trial permit and providing information required by regulatory bodies.

xxx. **Trial site:** A single site where one or more field trials of the same plant species are confined by a shared method of reproductive isolation. For example, three confined field trials of cotton surrounded by a shared 50 m isolation area would constitute a single trial site.

xxxi. **Trial site location**: The geographic location of a confined trial site *e.g.*, village, address and plot number.

xxxii. **Volunteers:** Self-sown plants of the same species as the regulated plant that may germinate and grow on the trial site and/or within the isolation distance.

4. STANDARD OPERATING PROCEDURES

The following SOPs should be followed for conducting the confined field trials of all regulated, genetically engineered plants in India.

A. STANDARD OPERATING PROCEDURE (SOP) FOR THE TRANSPORT OF REGULATED GENETICALLY ENGINEERED PLANT MATERIAL

A.1. Scope

A.1.1. This SOP applies to the transport of regulated, genetically engineered seed or propagable plant material for the purposes of import, export, inter-state movement and intra-state movement.

A.2. General Requirements

A.2.1. All regulated, genetically engineered seed or propagable plant material must be stored in secure containers/packets for transportation.

A.2.2. All regulated, genetically engineered seed or propagable plant material must be kept separate (secured in a primary container) from other plant material during transport.

A.2.3. All regulated genetically engineered seed or propagable plant material must be clearly labelled.

A.2.4. The Permitted Party will ensure that appropriate containers/packaging materials are supplied to all agents working on their behalf for the purpose of transporting regulated, genetically engineered seed or propagable plant material.

A.3. Specific Requirements for the Transport of Regulated Genetically Engineered Plant Material

A.3.1. The requirements of this section also apply to non-regulated seed (*e.g.*, conventional seed or genetically engineered seed that has previously been approved for commercial cultivation in India) that will accompany regulated, genetically engineered seed or propagable plant material when transported within the same secondary container.

A.3.2. Regulated, genetically engineered seed or propagable plant material is to be secured within a primary container as described in A.3.4.

A.3.3. Each sealed, primary container can contain only regulated, genetically engineered seed or propagable plant material derived from one event.

A.3.4. The primary container must be a sealable bag, envelope or package constructed of tear and moisture resistant material (*e.g.*, polythene bags, seed envelope, cardboard box).

A.3.5. The primary container must be placed within a sealable, leak-proof secondary container. Multiple primary containers can be placed within a single secondary container.

A.3.6. 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.

A.3.7. Primary and secondary containers used to transport regulated, genetically engineered seed or propagable plant material which are proposed to be re-used must be cleaned after use. Alternatively, primary and secondary containers must be destroyed (by autoclaving or burning).

A.3.8. Any residual seed or propagable material recovered during the process of cleaning must be rendered non-viable by heating, incineration or crushing.

A.3.9. Primary and secondary containers should be labelled in accordance with the requirements of Section A.4.

A.3.10. Prior to sending the material, the Transport In Charge must inform the Recipient of dispatch of the material as outlined in A.5.

A.4. Labelling of Containers

A.4.1. Primary containers should be labelled with an identifying number or name of the regulated plant material (*e.g.*, event name or number or other unique identifier) and the Dispatch Number found on the Record of Transport.

A.4.2. All secondary containers used to transport regulated plant material should be labelled to identify the Transport In Charge and Receiver and their emergency contact details in case of an accidental release.

A.5. Accompanying Documentation for the Transport of Regulated Plant Material

A.5.1. The Transport In-Charge must complete the following sections of the Record of Transport: contact details of Transport In-Charge and Recipient; Regulated Plant Material Identification; Pre-Transport Details; his/her Signature; and date of dispatch.

A.5.2. When multiple primary containers of regulated material are included within a single secondary container, a Transport Inventory List must be attached to the Record of Transport.

A.5.3. The Record of Transport, with attached Transport Inventory List if applicable, must be intimated in writing (email/fax/letter) to the Receiver before the consignment is sent.

A.5.4. The original Record of Transport, with attached Transport Inventory List if applicable, must be placed within the secondary container by the Transport In-Charge.

A.5.5. Copies of the Record of Transport, Transport Inventory List if applicable and other accompanying documents (*e.g.*, Plant Import Permit, Phytosanitary Certificate) must be retained by the Transport In-Charge.

A.6. Receipt of Transported Goods

A.6.1. When a consignment of regulated, genetically engineered 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 Record of Transport is absent from the consignment, the Recipient must contact the Transport In Charge and request that a copy be sent/transmitted immediately.

iii. Until such time as the Record of Transport 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 this SOP shall be followed.

A.6.2. The Recipient shall complete the details regarding Receipt of Consignment section of the original Record of Transport.

A.6.3. If the secondary container was damaged during transport, the Recipient must ensure that the primary container was not damaged and that none of the regulated plant material was lost by confirming the weight of the consignment.

A.6.4. If it is suspected that an accidental release has occurred, the corrective action requirements in Section A.7 must be followed.

A.6.5. A copy of the completed Record of Transport should be sent in writing (email or fax) by the Recipient to the Transport In-Charge.

A.7. Corrective Action In the Event of an Accidental Release

A.7.1. In the event of a confirmed accidental release of regulated, genetically engineered seed or propagable plant material during transport all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by heating, crushing, or burning.

A.7.2. The location of an accidental release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed of by heating, crushing, or burning. The period of monitoring will be determined in consultation with RCGM/GEAC.

A.7.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Recipient and copies will be submitted in writing preferably by fax to the Transport In-Charge, Permitted Party and RCGM/GEAC.

A.7.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

B. STANDARD OPERATING PROCEDURE (SOP) FOR THE STORAGE OF REGULATED GENETICALLY ENGINEERED PLANT MATERIAL

B.1. Scope

B.1.1. This SOP applies to the storage of regulated, genetically engineered plant material in India.

B.2. Specific Requirements for the Storage of Regulated Plant Material

B.2.1. The Permitted Party/Facility In-Charge must ensure the suitability of all storage facilities prior to accepting consignments of regulated plant material.

B.2.2. A storage area must be a fully enclosed space (*e.g.*, boxes, almirahs, cabinets, closet etc) and must be secured by a lockable door. If present, any windows must be closed and locked.

B.2.3. Where a storage area may be used to store multiple samples of regulated plants, each sample should be stored separately in a sealed, labelled container.

B.2.4. All storage areas must be clearly labelled as containing regulated plant material in accordance with the requirements of Section B.3 of this SOP.

B.2.5. Access to storage areas must be limited to personnel authorized by the Permitted Party or Facility In-Charge.

B.2.6. Areas or units designated for storage of regulated plant material must be cleaned immediately following the period of storage.

B.2.7. The addition of regulated plant material to the storage area or removal of regulated plant material from the storage area must be recorded on the Record of Storage Inspection and Inventory.

B.2.8. Any sample of regulated plant material removed from storage for the purpose of disposal must be rendered non-viable by heating, crushing, or burning.

B.3. Labelling of the Storage Area

B.3.1. The storage area must be labelled as containing regulated plant material (see Section B.8 for a sample label).

B.3.2. The storage area label should be affixed to the point of entry to the storage area.

B.4. Inspection of the Storage Area

B.4.1. Inspection of the storage area must be completed monthly by the Permitted Party/Facility In-Charge to ensure that storage conditions are maintained in accordance with this SOP. Each inspection is to be recorded on the Record of Storage Inspection and Inventory.

B.4.2. The Record of Storage Inspection and Inventory is to be retained by the Permitted Party/Facility In-Charge.

B.5. Inspection by Regulatory Officials

B.5.1. Access to the storage facility for the purpose of inspection will be provided to regulatory officials/ monitoring committees upon request for official purposes preferably during regular working hours.

B.6. Occurrence of Non-Compliance

B.6.1. In situations where non-compliance with the terms and conditions of the confined field trial permit is confirmed, the Permitted Party will notify RCGM/GEAC immediately by telephone and positively within 24 hours in writing. RCGM/GEAC will provide the Permitted Party with the appropriate course of remedial action.

B.7. Corrective Action in the Event of an Accidental Release

B.7.1. In the event of a confirmed accidental release of regulated plant material from storage all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by dry heat, steam heat, crushing, or burning.

B.7.2. The location of an accidental release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed of by dry heat, steam heat, crushing, or burning. The period of monitoring will be determined in consultation with RCGM/GEAC.

B.7.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Facility In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

B.7.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

B.8. Sample Storage Area Label

THIS STORAGE AREA CONTAINS REGULATED GENETICALLY ENGINEERED PLANT MATERIAL

Storage Site Address
Room Number or Description:

ACCESS TO THIS STORAGE AREA IS LIMITED TO PERSONNEL DESIGNATED BY THE PERMITTED PARTY:

Name of facility in-charge

Room no.

Telephone number

In case of emergency or damage to the storage area, contact the facility In-Charge immediately

C. STANDARD OPERATING PROCEDURE (SOP) FOR THE MANAGEMENT OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

C.1. Scope

C.1.1. This SOP applies to all confined field trials of regulated, genetically engineered plants in India.

C.2. Requirements for Planting Confined Field Trials (All Crops)

C.2.1. All equipment and tools used to seed or plant confined field trials or used in the maintenance of the trial site must be cleaned on the trial site prior to their removal to eliminate unintended transport of regulated plant material from the trial site. Acceptable methods of cleaning include hand cleaning, compressed air, vacuuming of remaining seed or high-pressure water. Any plant material recovered must be rendered non-viable by burning or burial on the trial site.

C.2.2. A map of the trial site must be prepared by the Trial In-Charge and appended to the Record of Planting. Instructions for the preparation of maps are provided in Box 1.

C.2.3. A Record of Planting must be completed for each field trial site. A copy of the Record of Planting, with the appended map, must be submitted to RCGM/GEAC within seven (7) days following the completion of planting. The original Record of Planting must be retained by the Trial In-Charge, and copies made available to regulatory officials upon request.

C.2.4. The Trial In-Charge must mount a Notice Board at the trial site indicating the purpose and duration of the confined field trials conducted at the trial site and the authorization under which the confined field trials were approved.

C.2.5. The Trial In-Charge must ensure that only personnel authorized by the Permitted Party are permitted on the trial site. A bound book including the name, address and affiliation must be maintained of all personnel who enter the trial site

C.3. Performance Requirements for Confined Field Trials (All Crops)

C.3.1. All corners of each trial site will be clearly marked with reference to physical markers to permit identification of the trial site during the period of the trial and the post-harvest period.

C.3.2. Any plant material removed during maintenance of the trial (*e.g.*, thinning of plantlets or removal of any plant parts) must be rendered non-viable by burning or burial on the trial site.

C.3.3. All confined field trial sites must be reproductively isolated from plants of the same or any other sexually compatible species that are not part of the trial by spatial isolation. Isolation distances are crop specific and the allowable isolation distance will be indicated by RCGM/GEAC in the letter of approval for the confined field trial.

C.3.4. The isolation area must be continuous and completely surround the confined trial site.

C.3.5. The Trial In-Charge must ensure that the trial site and surrounding isolation area are kept free of all prohibited plants by implementing a program of regular monitoring and removal of any prohibited plants (see section C.4).

C.3.6. Any prohibited plants within the isolation area must be removed before they flower.

C.3.7. If any prohibited plants within the isolation area are permitted to flower, a breach of reproductive isolation will have occurred.

C.3.8. Any prohibited plants removed from the isolation distance must be rendered non-viable by burning or burial on the trial site.

C.4. Monitoring of the Field Trial by the Trial In-Charge

C.4.1. The following are requirements when spatial isolation is used to reproductively isolate the field trial:

i. The Trial In-Charge or his/her designate must monitor the trial site at least ONCE EVERY TWO WEEKS from the time of planting until the time of harvest of the trial.

ii. The Record of Spatial Isolation will be used to document all monitoring and field activities needed to demonstrate reproductive isolation of the trial site.

iii. The growth stage of any prohibited plants found on the trial site should be recorded during monitoring. To facilitate this, a growth stage key should be made available to all monitoring personnel to facilitate consistency in identifying growth stages. An example of a growth stage key is provided in Box 2.

C.5. Inspection by regulatory officials

C.5.1. Access to the trial site for the purpose of inspection will be provided to regulatory officials/monitoring committees upon request, for official use only and preferably during regular working hours.

C.6. Corrective Action in the Event of an Accidental Release

C.6.1. In the event of a confirmed accidental release of regulated plant material from the trial site, all attempts shall be made to recover as much of the regulated material as possible. Recovered material will be rendered non-viable by burning or burial on the trial site.

C.6.2. If an accidental 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 material occurs. The period of monitoring will be determined in consultation with RCGM/GEAC.

C.6.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

C.6.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

C.7. Record Keeping

C.7.1. The Record of Planting and map for each trial site will be retained by the Trial In-Charge and one copy will be submitted to RCGM/GEAC within 7 days of planting.

C.7.2. As appropriate, original copies of the Record of Spatial Isolation for each trial site will be retained by the Trial In-Charge.

C.7.3. All records associated with the management of confined field trials must be available for inspection by RCGM/GEAC, MEC, State Government Officials, State Agricultural University or their nominee upon request.

C.7.4. At the end of the post-harvest period when all requirements for management of the confined field trial site have been completed, the original copies of all reports related to conduct of the trial will be forwarded to the Permitted Party by the Trial In-Charge.

C.7.5. The Permitted Party will archive copies of the following records for all permitted field trials for a minimum of five (5) years, whether or not the regulated material is authorized for commercial release: Record of Planting, Record of Spatial Isolation, Record of Corrective Action (when applicable).

BOX 1: INSTRUCTIONS FOR PREPARATION OF MAPS

1. 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.
2. A map of the trial site will be prepared by the Trial In-Charge and appended to the Record of Planting.
3. Maps must provide sufficient detail to allow regulatory officials to locate each field trial site during the planting season and any required period of post-harvest land use restriction.
4. Maps must provide details on the layout of the site and distances between the field trial site and surrounding features.
5. The dimensions of the trial site and distances to physical landmarks must be accurately reported.
6. The following items shall be included on each map of a field trial site:
   a. Trial In-Charge's name and contact details.
   b. Permit number from the regulatory authority.
   c. Legal or descriptive land location (name of the village, taluka, district, state).
   d. Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.
   e. Total area planted with the regulated material, including negative controls and any border or guard rows when used (acres or square meters).
   f. Label all fields within the isolation area by the common name of the crop.
   g. Indicate any fields of same/related crops that fall within, or border on, the isolation area.
   h. Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, garden, orchard, forests, and woodlots, hedgerows), wherever reasonable.
   i. Planting date.
   j. Compass directions, with North at the top of the page.

BOX 2: KEY TO COTTON GROWTH STAGES

This key is provided to standardize the recording of cotton growth stages when monitoring the trial site.

Growth stage	Days after planting
Emergence	5-15
4th true leaf	20-30
1st square (pinhead)	30-45
1st bloom	50-80
Cut out	80-120
Defoliation	120-170
Harvest	130-180

D. STANDARD OPERATING PROCEDURE (SOP) FOR THE HARVEST OR TERMINATION OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

D.1. Scope

D.1.1. This SOP applies to the harvest or termination of all confined field trials of regulated, genetically engineered plants in India.

D.2. Requirements for Harvest of Confined Field Trials

D.2.1. The requirements in this section apply to the harvest or termination of all confined field trials.

D.2.2. All equipment and tools used during harvest or termination of confined field trials must be cleaned on the trial site prior to their removal to eliminate unintended transport of regulated plant material from the trial site. Acceptable methods of cleaning include hand cleaning, compressed air, vacuuming of remaining seed, and high-pressure water. Any plant material recovered must be rendered non-viable by burning or burial on the trial site.

D.2.3. A Record of Harvest/Termination will be completed for each field trial site. This Record will document the amounts and fate of all harvested material and the disposal of any unwanted plant material on the trial site. The Record of Harvest/Termination must be retained by the Trial In-Charge, and copies made available to regulatory officials/monitoring committees upon request.

D.3. Destruction of Regulated Transgenic Plant Material

D.3.1. Plant material from a confined field trial site, including border rows when these were planted, that is not retained for research purposes will be destroyed by burning or burial on the trial site.

D.3.2. Animal grazing of residual plant material that may remain on the trial site after harvest or termination is prohibited.

D.3.3. The Trial In-Charge must monitor harvest or termination at trial sites to ensure that all regulated plant material that is not retained is disposed of as described in D.2.2.

D.4. Transport of Harvested Materials from the Trial Site

D.4.1. The transport of all plant material from the trial site will be conducted in accordance with the Standard Operating Procedure for the Transport of Regulated Genetically Engineered Plant Material.

D.5. Inspection By Regulatory Officials

D.5.1. Access to the trial site for the purpose of inspection will be provided to regulatory officials/monitoring committees upon request for official purposes preferably during regular working hours.

D.6. Occurrence of Non-Compliance

D.6.1. In situations where non-compliance with the terms and conditions of the confined field trial permit is confirmed, the Permitted Party will notify RCGM/GEAC immediately by telephone and positively within 24 hours in writing. RCGM/GEAC will provide the Permitted Party with the appropriate course of remedial action.

D.7. Corrective Action In The Event Of An Accidental Release

D.7.1. In the event of a confirmed accidental release of regulated plant material all attempts shall be made to recover as much of the regulated material as possible. Recovered material will be rendered non-viable by burning or burial on the trial site.

D.7.2. If an accidental 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 material occurs. The period of monitoring will be determined in consultation with RCGM/GEAC.

D.7.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

D.7.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

D.8. Record Keeping

D.8.1. The Record of Harvest/Termination must be completed by the Trial In-Charge immediately after harvest or termination of confined field trials at a trial site. This record must be verified and signed by a member of the Monitoring Agency or any nominee of RCGM/GEAC/SBCC/DLC/SAU authorized by RCGM/GEAC to conduct a trial site inspection during harvest.

D.8.2. A copy of the Record of Harvest/Termination must be submitted to RCGM/GEAC within 15 days of harvest/termination of confined field trials at the trial site. One copy is to be retained by the Trial In-Charge and one copy will be submitted to, and retained by, the Permitted Party

D.8.3. All records associated with the harvest or termination of confined field trials must be available for inspection by RCGM/GEAC, MEC, State Government Officials, State Agricultural University or their nominee upon request.

D.8.4. At the end of the post-harvest period when all requirements for management of the confined field trial site have been completed, the original copies of all reports related to conduct of the trial will be forwarded to the Permitted Party.

D.8.5. The Permitted Party will archive copies of the following records for all permitted field trials for a minimum of five (5) years, whether or not the regulated material is authorized for commercial release: Record of Harvest/Termination, Record of Corrective Action (when applicable).

E. STANDARD OPERATING PROCEDURE (SOP) FOR THE POST-HARVEST MANAGEMENT OF CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS

E.1. Scope

E.1.1. This SOP applies to all confined field trials of regulated, genetically engineered plants during the mandated post-harvest period.

E.2. General Requirements

E.2.1. During the post-harvest period, trial sites cannot be used as pasture for animal grazing as regulated plants may be present as volunteers.

E.3. Requirements for Post-Harvest Management of Trial Sites, Case by Case, as Specified by Regulatory Authorities

E.3.1. The mandatory post-harvest period for confined field trial sites is crop specific and will be indicated by RCGM/GEAC in the letter of approval for the confined field trial.

E.3.2. The post-harvest period begins immediately upon harvest or termination of the confined field trials at the trial site.

E.3.3. Ownership and/or control of the trial site must be secured by the Permitted Party for the post-harvest period. This assurance is to be obtained in writing before the trial site is planted.

E.3.4. During the post-harvest period the trial site may not be planted with the same species as was planted during the confined field trial.

E.3.5. During the post-harvest period, the Trial In-Charge must ensure that any volunteers or prohibited plants are removed from the trial site before flowering and are rendered non-viable by burning or burial on the trial site.

E.3.6. If any prohibited plants are permitted to flower, the post-harvest period will be extended by an additional term equal to the post-harvest period.

E.3.7. Only the trial site will be subject to land use restrictions and monitoring during the post-harvest period, with the following exception: when a breach of reproductive isolation was determined to have occurred in the isolation area during the field trial period the isolation area will also be subject to land use restrictions and monitoring during the post-harvest period.

E.3.8. Post-harvest monitoring and related activities must be recorded in the Record of Post-Harvest Inspection.

E.4. Monitoring of The Post-Harvest Trial Site

E.4.1. During the post-harvest period, the Trial In-Charge must ensure that the trial site is monitored for the presence of volunteers or other prohibited plants at least ONCE EVERY FOUR WEEKS.

E.4.2. At the time of monitoring, the growth stage of any volunteers and/or prohibited plants will be recorded on the Record of Post-Harvest Inspection. To facilitate this, a growth stage key should be made available to all monitoring personnel to facilitate consistency in identifying growth stages. An example of a growth stage key is provided in Box 2.

E.5. Corrective Action In The Event Of An Accidental Release

E.5.1. In the event of a confirmed accidental release of regulated plant material all attempts shall be made to recover as much of the regulated material as possible. Recovered material will be rendered non-viable by burning or burial on the trial site.

E.5.2. If an accidental 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 material occurs. The period of monitoring will be determined in consultation with RCGM/GEAC.

E.5.3. The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

E.5.4. Any other corrective actions will be determined in consultation with RCGM/GEAC.

E.6. Record Keeping

E.6.1. The Record of Post-Harvest Monitoring will be completed by the Trial In-Charge for the duration of the post-harvest period.

E.6.2. All records associated with the management of confined field trials must be available for inspection by RCGM/GEAC, MEC, State Government Officials, State Agricultural University or their nominee upon request.

E.6.3. At the end of the post-harvest period when all requirements for management of the confined field trial site have been completed, the original copies of all reports related to the trial site will be forwarded to the Permitted Party.

E.6.4. The Permitted Party will archive copies of the following records for all permitted field trials for a minimum of five (5) years, whether or not the regulated material is authorized for commercial release: Record of Post-Harvest Monitoring, Record of Corrective Action (when applicable).

5. REVIEW OF SOPs

5.1. These SOPs will be reviewed by RCGM/GEAC at least annually.

5.2. After review, any revised SOPs will be posted to the DBT website (www.dbtbiosafety.nic.in), provided to all MECs, SAUs, IBSCs, SBCCs and DLCs, and will be referred to in confined field trial permits.

6. CORRECTIVE ACTION IN CASE OF ACCIDENTAL RELEASE

In the event of a confirmed accidental release of regulated plant material at any stage, all attempts shall be made to recover as much of the regulated material as possible. Recovered material must be rendered non-viable by dry heat, steam heat, crushing, or burning.

The location of an accidental release must be marked and monitored to ensure that any progeny plants arising from the regulated plant material are rendered non-viable and disposed of by dry heat, steam heat, crushing, or burning. The period of monitoring will be determined in consultation with RCGM/GEAC.

The accidental release incident will be immediately documented in a Record of Corrective Action. The original Record of Corrective Action is to be retained by the Trial In-Charge and copies will be submitted by facsimile to the Permitted Party and RCGM/GEAC.

Any other corrective actions will be determined in consultation with RCGM/GEAC.

RECORD OF CORRECTIVE ACTION

INSTRUCTIONS:

- ❒ The Record of Corrective Action is used to document all corrective actions taken to manage or resolve a situation involving the accidental release of regulated plant material during transport and/or storage or any breach of the terms and conditions of authorization of the confined field trial or during the post-harvest monitoring period.

- ❒ A copy of this record of Corrective Action, together with any other relevant records (*e.g.* , Record of Transport, Record of Storage Inspection, Record of Spatial Isolation, Record of Harvest, *etc* .), should be forwarded to the Permitted Party and RCGM/GEAC.

PLEASE PRINT CLEARLY

PERMITTED PARTY

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

RECORD INITIATED BY

Name _____

Position _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

RECORD OF CORRECTIVE ACTION (cont'd)

ACTIVITY REQUIRING CORRECTIVE ACTION

Indicate the category of activity requiring corrective action and then complete the relevant information requirements under transportation and storage, or trial site.

☐ transport ☐ storage ☐ planting ☐ monitoring ☐ harvesting ☐ Other

If other, describe below

IDENTIFICATION OF AFFECTED REGULATED PLANT

Permit number

Plant species

Approximate amount of affected material

Form of material ☐ seeds ☐ tubers ☐ transplants ☐ other, describe below

TRANSPORT AND STORAGE

Consignment

Item number

Facility name

Storage location identifier

Building name

Room number or description

Address of facility

RECORD OF CORRECTIVE ACTION (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

Method of reproductive isolation ☐ spatial isolation ☐ crop termination ☐ other, describe below

_____

IDENTIFICATION OF COMPLIANCE ISSUE

Check all that apply

- ☐ unauthorized shipment
- ☐ primary shipping container breached
- ☐ accidental release during transport
- ☐ accidental release during storage
- ☐ other, describe below
- ☐ breach of spatial isolation
- ☐ article lost during shipment
- ☐ Record of Transport missing
- ☐ received at wrong destination
- ☐ prohibited plants present on post-harvest site

_____

DESCRIPTION OF CORRECTIVE ACTION TAKEN

Check all that apply

- ☐ destruction of regulated material
- ☐ removal of prohbited plants
- ☐ destruction of neighbouring crop
- ☐ other, describe below
- ☐ recovery of spilled material
- ☐ destruction of trial
- ☐ imposition of post harvest restrictions
- ☐ imposition of spatial isolation zone

_____

RECORD OF CORRECTIVE ACTION (cont'd)

ADDITIONAL COMMENTS AND OBSERVATIONS

VERIFICATION

This activity has been carried out to meet the specific authorization permit conditions for storage, transport and/or conduct of confined field trials of regulated plant material.

Signature of Trial In-Charge

Date signed

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

THIS SECTION TO BE COMPLETED BY THE AUTHORIZED PARTY ONLY

COMMUNICATION WITH REGULATORY OFFICIALS

Name of official first contacted

Department or office

Telephone

Fax

E-mail

Summarize communication outcomes, including agreed options for risk management. Itemize all communications, recording date and individuals involved. Attach any written correspondence or transcripts of oral communications.

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 FIFTEEN (15) 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 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

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 ☐ water ☐ other, describe below

_____

ON SITE DISPOSITION OF PLANT MATERIAL

☐ burning ☐ burial

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 plants ☐ vegetative material	☐ yes ☐ no
2.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
3.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
4.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
5.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
6.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
7.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
8.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
9.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no
10.				☐ grain/seed ☐ whole plants ☐ vegetative material	☐ yes ☐ no

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

Date signed

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

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

TRANSPORTATION OF REGULATED PLANT MATERIAL

Is a Record of Transport for all material transported to the trial site attached?

☐ yes ☐ no Consignment No. _____

Was any regulated plant material dispatched from the trial site during or after planting? If yes, enter consignment number.

☐ yes ☐ no Consignment No. _____

RECORD OF PLANTING (cont'd)

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.				

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

Date signed

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

RECORD OF POST HARVEST MONITORING

INSTRUCTIONS:

- ❒ Trial sites should be inspected for the presence of prohibited plants at least ONCE EVERY TWO (2) WEEKS during the growing season for the ONE YEAR post harvest period. Growth stages of any prohibited plants must be recorded. The post-harvest period begins on the date of harvest/termination of the trial.

- ❒ If any breach of reproductive isolation occurred during performance of the trial, the post-harvest restrictions, including the monitoring requirements for prohibited plants, will apply to the trial site and the spatial isolation area around the trial site.

- ❒ During the post-harvest period, if any prohibited plants are permitted to flower within the area under post-harvest restrictions, an additional post-harvest period of one year will be applied. The incident and any corrective action taken should be recorded on a Record of Corrective Action.

- ❒ The Record of Post-Harvest Inspection should be retained by the Trial In-Charge and made available to regulatory officials/monitoring committees upon request. Upon completion, a copy of the signed Record of Post-Harvest Inspection should be forwarded to the Permitted Party.

- ❒ In the event of a breach of reproductive isolation, the Permitted Party must 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 POST HARVEST MONITORING (cont'd)

TRIAL SITE

Site location _____

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

Legal or descriptive land location _____

Area under post harvest restriction ☐ trial area only ☐ trial area + isolation area

Post harvest year ☐ 1 year ☐ 2 year ☐ 3 year

REGULATED PLANT MATERIAL PREVIOUSLY PLANTED AT THE TRIAL SITE

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

DATA SHEET FOR RECORDING MONITORING FOR THE PRESENCE OF PROHIBITED PLANTS

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
1.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
2.		☐ Yes ☐ No		
Additional comments and observations			**Signature**	

RECORD OF POST HARVEST MONITORING (cont'd)

DATA SHEET FOR RECORDING MONITORING FOR THE PRESENCE OF PROHIBITED PLANTS (cont'd)

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
3.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
4.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
5.		☐ Yes ☐ No		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
6.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
7.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
8.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
9.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

RECORD OF POST HARVEST MONITORING (cont'd)

DATA SHEET FOR RECORDING MONITORING FOR THE PRESENCE OF PROHIBITED PLANTS (cont'd)

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
10.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

ADDITIONAL COMMENTS AND OBSERVATIONS

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

Date signed

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

RECORD OF SPATIAL ISOLATION

INSTRUCTIONS:

- ❒ The spatial isolation area as mandated in the permit from RCGM/GEAC should be inspected at least ONCE EVERY TWO (2) WEEKS during the growing season for the presence of prohibited plants.
- ❒ If any prohibited plants within the isolation area are permitted to complete flowering, a breach of reproductive isolation will have occurred.
- ❒ Growth stages of any prohibited plants must be recorded.
- ❒ This Record of Spatial Isolation should be used to record every inspection, including removal of plants as may be necessary. Monitoring should be carried out by the Trial In-Charge or a person authorized by the Trial In-Charge.
- ❒ This Record of Spatial Isolation should be retained by the Trial In-Charge and made available to regulatory officials/monitoring committees upon request.
- ❒ In the event of a breach of reproductive isolation, 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 SPATIAL ISOLATION (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

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 SPATIAL ISOLATION (cont'd)

DATA SHEET FOR RECORDING MONITORING FOR THE PRESENCE OF PROHIBITED PLANTS

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
1.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
2.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
3.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
4.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
5.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
6.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
7.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

RECORD OF SPATIAL ISOLATION (cont'd)

DATA SHEET FOR RECORDING MONITORING FOR THE PRESENCE OF PROHIBITED PLANTS (cont'd)

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
8.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
9.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

S. No.	Date inspected	Prohibited plants present	Growth stage of any prohibited plants	Method of destruction of any prohbited plant material
10.		☐ yes ☐ no		
Additional comments and observations			**Signature**	

ADDITIONAL COMMENTS AND OBSERVATIONS

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

Date signed

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

RECORD OF STORAGE INSPECTION

INSTRUCTIONS:

- ❒ This Record of Storage Inspection should be completed ONCE EVERY FOUR (4) WEEKS by the Facility In-Charge to ensure that storage conditions are maintained so that unintended releases of regulated transgenic plant material do not occur.
- ❒ This Record of Storage Inspection should be retained by the Facility In-Charge and made available to regulatory officials upon request.
- ❒ In the event of an Accidental Release of the regulated plant material during storage, the Permitted Party should be immediately notified 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 _____

FACILITY IN-CHARGE

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

RECORD OF STORAGE INSPECTION (cont'd)

STORAGE FACILITIES

Building name _____

Room number/description _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

INSPECTION CHECK LIST

Storage area secure	☐ yes	☐ no
Storage area clean and free of any waste or debris	☐ yes	☐ no
Storage area clearly labelled	☐ yes	☐ no
Monthly records of storage inspection available	☐ yes	☐ no

In the event of a **NO** answer to any of the above, provide additional explanation below.

_____

_____

FACILITY IN-CHARGE VERIFICATION

This activity has been carried out to meet the specific authorization permit conditions for storage of regulated plant material.

Signature of Facility In-Charge _____ Date signed _____

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

RECORD OF STORAGE

INSTRUCTIONS:

- ❒ This Record of Storage should be completed for each lot of regulated plant material / seed placed into storage and each Record of Storage should be identified with a unique inventory control number. One or more copies of the Record of Inventory Change can be attached to the Record of Storage to document any removals of material from storage.
- ❒ The designated official of the Permitted Party is the person responsible for the regulated plant material in storage.
- ❒ No regulated plant material should be removed from storage for transport outside of the facility without completion of a Record of Transport.
- ❒ In the event of an Accidental Release of the regulated plant material during storage, the Permitted Party should be immediately informed by the designated official by telephone and fax. 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 _____

DESIGNATED OFFICIAL / FACILITY IN-CHARGE

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

RECORD OF STORAGE (cont'd)

STORAGE FACILITIES

Building name _____

Room number/description _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

TRANSGENIC PLANT MATERIAL IDENTIFICATION

Permit number _____

Plant species _____

Event name _____

INVENTORY INFORMATION

Amount of material placed in storage _____

First date of storage _____

CREATION OF RECORD OF STORAGE

Signature of Designated Official/Facility In-Charge _____ Effective date _____

TERMINATION OF RECORD OF STORAGE

Reason for termination of storage ☐ all material removed ☐ destruction of material ☐ other, detail below

_____

_____

Signature of Designated Official/Facility In-Charge _____ Effective date _____

RECORD OF STORAGE (cont'd)

RECORD OF INVENTORY CHANGE

An entry into this Record of Inventory Change should be made each time an amount of regulated material is removed from storage inventory.

When the final lot of regulated material is removed from storage, the associated Record of Storage should be updated and the Record of Inventory Change should be attached. Only authorized persons should remove regulated material from storage and no material should be removed from storage for transport outside of the facility without completion of a Record of Transport.

REMOVALS OF MATERIAL FROM STORAGE

S. No.	Removal date (DD-MM-YY)	Amount removed	Amount remaining	Signature of Designated Official/Facility In-Charge

RECORD OF TRANSPORT

INSTRUCTIONS:

- ❒ This Record of Transport should be completed for every consignment of regulated transgenic plant material.
- ❒ For consignment of a single item of regulated plant material, complete only the information on this page. For consignments of multiple items, complete and affix one or more copies of the inventory list on page 2.
- ❒ Following completion of this record by the Transport In-Charge, one copy should be forwarded to the Recipient. Following completion of this record by the Recipient, one copy should be returned to the Transport In-Charge and one copy should be forwarded to the Permitted Party.
- ❒ In the event of an accidental release during transport, a Record of Corrective Action must be initiated.

PLEASE PRINT CLEARLY

PERMITTED PARTY

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

TRANSPORT IN-CHARGE

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

RECORD OF TRANSPORT (cont'd)

RECIPIENT

Name _____

Organization _____

Address _____

_____

_____

Telephone _____ Fax _____

E-mail _____

I. REGULATED PLANT MATERIAL IDENTIFICATION

RCGM/GEAC Permit Number _____

Plant species _____

No. / names of varieties / hybrids / checks _____

_____

_____

Specify exact amount of material of each of the above. _____

_____

_____

Transported (g or number) _____

Form of material ☐ seed ☐ tuber ☐ transplants ☐ other, describe below

_____

Identify any chemical treatment of the material _____

II. PRE-TRANSPORT DETAILS (to be completed by Transport In-Charge)

Method of transport ☐ rail ☐ road ☐ air ☐ ship ☐ other, specify below

RECORD OF TRANSPORT (cont'd)

II. PRE-TRANSPORT DETAILS (cont'd)

Name and contact details of transporter _____

_____

Primary container ☐ plastic bag ☐ paper bag ☐ other, describe below

_____

Type of secondary container _____

Condition of container ☐ new ☐ used

_____

Accompanying documentation _____

Movement permit _____

Phytosanitary certificate _____

Other(s), describe _____

_____

SHIPMENT VERIFICATION

SIGNATURE OF TRANSPORT IN-CHARGE _____ Shipment date _____

III. RECEIPT OF SHIPMENT (to be completed by recipient)

All inventory checked and complete ☐ yes ☐ no

All accompanying documentation received ☐ yes ☐ no

Condition of shipping containers

Primary container ☐ intact ☐ damaged

Secondary container ☐ intact ☐ damaged

Other details on condition of shipping containers or documentation _____

_____

RECEIPT VERIFICATION

_____ _____

Signature of recipient Receipt date

RECORD OF TRANSPORT (cont'd)

IV. REGULATED TRANSGENIC PLANT MATERIAL INVENTORY LIST

S. No. ________ Event name ______________________________

Permit number ______________________________

Exact amount of material transported (g or number) ______________

Form of plant material
☐ seed ☐ tubers ☐ transplants ☐ rhizomes
☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ______________

S. No. ________ Event name ______________________________

Permit number ______________________________

Exact amount of material transported (g or number) ______________

Form of plant material
☐ seed ☐ tubers ☐ transplants ☐ rhizomes
☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ______________

S. No. ________ Event name ______________________________

Permit number ______________________________

Exact amount of material transported (g or number) ______________

Form of plant material
☐ seed ☐ tubers ☐ transplants ☐ rhizomes
☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ______________

S. No. ________ Event name ______________________________

Permit number ______________________________

Exact amount of material transported (g or number) ______________

Form of plant material
☐ seed ☐ tubers ☐ transplants ☐ rhizomes
☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ______________

RECORD OF TRANSPORT (cont'd)

IV. REGULATED TRANSGENIC PLANT MATERIAL INVENTORY LIST (cont'd)

S. No. ________ Event name ____________________

Permit number ____________________

Exact amount of material transported (g or number) ____________________

Form of plant material ☐ seed ☐ tubers ☐ transplants ☐ rhizomes ☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ____________________

S. No. ________ Event name ____________________

Permit number ____________________

Exact amount of material transported (g or number) ____________________

Form of plant material ☐ seed ☐ tubers ☐ transplants ☐ rhizomes ☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ____________________

S. No. ________ Event name ____________________

Permit number ____________________

Exact amount of material transported (g or number) ____________________

Form of plant material ☐ seed ☐ tubers ☐ transplants ☐ rhizomes ☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ____________________

S. No. ________ Event name ____________________

Permit number ____________________

Exact amount of material transported (g or number) ____________________

Form of plant material ☐ seed ☐ tubers ☐ transplants ☐ rhizomes ☐ budwood/shoots ☐ whole plants

Identify any chemical treatment of the material ____________________

GUIDELINES FOR THE MONITORING OF CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

GUIDELINES FOR THE MONITORING OF CONFINED FIELD TRIALS OF REGULATED, GE PLANTS

1 INTRODUCTION

The conduct of confined field trials of regulated genetically engineered plants in India is regulated under the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells" notified under the Environment (Protection) Act, 1986, commonly referred as Rules, 1989. These rules are implemented by the Ministry of Environment and Forests (MoEF) and Department of Biotechnology (DBT) and State Governments. Six competent authorities have been provided for in the Rules: the Recombinant DNA Advisory Committee (RDAC), the Review Committee on Genetic Manipulation (RCGM), the Genetic Engineering Approval Committee (GEAC), Institutional Biosafety Committees (IBSCs) attached to every organization engaged in recombinant-DNA research, State Biotechnology Coordination Committees (SBCCs) and District Level Committees (DLCs). While the role of the RDAC is strictly advisory in nature, RCGM and GEAC have regulatory responsibilities.

Some of these organizations have been delegated authority under the Rules, 1989 to monitor confined field trial sites for the purpose of ascertaining compliance with the terms and conditions of authorization. These include members of the RCGM's Monitoring cum Evaluation Committee (MEC), SBCCs, DLCs, and monitoring teams of state agricultural universities (SAUs). Monitoring may be undertaken at various times during the conduct of a confined field trial, including during planting, during the growing season, at harvest, and during the period of post-harvest land use restriction. Monitoring agencies also have the authority to inspect contained facilities that may be used for the storage of regulated genetically engineered plant material.

The purpose of these guidelines is to provide clear and concise information to help those individuals designated as members of monitoring teams in the aforementioned monitoring agencies.

2 SCOPE

This document provides information about program for monitoring of confined field trials of regulated genetically engineered plants in India. The information provided herein is intended to provide guidance to designated members of monitoring teams who have been given responsibility of determining whether the conduct of a confined field trial, including the condition of the trial site, or storage facility, and availability of relevant documentation and records, are in compliance with the terms and conditions of *permit.* The guidance contained in this document is consistent with the "Guidelines for the Conduct of Confined Field Trials of Regulated, Genetically Engineered Plants in India" and related Standard Operating Procedures (SOPs).

3 TERMINOLOGY

Accidental release: Any unintended release of regulated plant material into the environment, food and/or feed chains. For the purposes of these Guidelines, any breach of the authorized terms and conditions for reproductive isolation of the confined trial site shall be considered an accidental release. Accidental release also includes the spillage, theft, or encroachment by unauthorized persons of regulated GE plant material during transportation, storage within a contained facility, or during any other activity associated with the conduct of a confined field trial. Any accidental release shall be subject to risk assessment, and any necessary corrective actions shall be at the cost of the applicant or permitted party.

Anthesis: The time of flowering or pollination. Anthesis is complete when flowering or pollination is complete.

Applicant: The Applicant must be a permanent resident of India or must designate an Authorized Signatory (AS) who is a permanent resident of India. Where an AS is used, there must be a formal, legal agreement indicating the AS is acting on behalf of the Applicant and both under the jurisdiction of any Court of Law of India. A copy of this agreement must be submitted to the Regulatory Authorities along with the confined field trial application. The Applicant need not be the breeder/developer or owner of the regulated plant, in which case a signed statement is required from the breeder/developer or owner authorizing representation by the Applicant or the designated AS. All correspondence with respect to the application for a confined field trial, including the notification of authorization, will be addressed to the Applicant, or when appropriate, the AS.

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.

Confined Field Trial: A confined field trial is a field experiment of a regulated GE plant under terms and conditions that are intended to mitigate the establishment and spread of the plant. A single confined field trial may be comprised of one or more varieties/hybrids of a single event of a single plant species that are subject to the same terms and conditions of confinement which include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. The field trials are categorized into two types: Biosafety Research Level I and Biosafety Research Level II trials.

Construct: An engineered DNA fragment containing, but not limited to, the DNA sequences to be integrated into the genome of the target plant.

Early termination: Any termination of a confined field trial before the anticipated completion date.

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.

Facility In-charge: The person designated by the permitted party as responsible for the storage (before or at planting, during planting and after harvest) of regulated, genetically engineered plant material.

Isolation distance: A mandated distance used to spatially separate a confined field trial from the nearest plant of the same or any sexually compatible species. Minimum spatial isolation distances vary depending on the reproductive biology of the plant species, and minimum distances for a number of plant species have been established by the RCGM.

Permitted Party: The Applicant or designated AS will be considered the 'Permitted Party' for the purposes of authorization and is the person who shall accept responsibility for compliance with the terms and conditions of the permit. The 'Permitted Party' may designate a Trial-in-Charge, who will be responsible for ensuring compliance with the requirements of authorization as specified by the Regulatory Authority.

Physical landmarks: Landmarks used to identify or designate boundaries of a confined field trial site (*e.g.*, telephone poles, fences, alleys or roads).

Plant material: Propagable material (*e.g.*, seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagable material (*e.g.*, leaves, devitalized 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.

Propagable: Any plant or plant part that can be used in the field to regenerate a whole plant under field conditions.

Regulated plant: Any plant produced through genetic engineering, including seed or propagable plant material

derived from that plant, which has not been authorized by the Regulatory Authorities for commercial cultivation pursuant to the Rules, 1989 of the Environmental Protection Act, 1986.

Regulatory Authority: As regards confined field trials, RCGM is the regulatory authority responsible for authorizing Biosafety Research Level I trials and GEAC is the regulatory authority responsible for authorizing Biosafety Research Level II trials.

Reproductive isolation: Refers to the means used to prevent movement of plant material, particularly pollen, from a confined field trial site.

Sexually compatible: Ability of a plant to cross-pollinate with other cultivated plants of the same species, or with wild plants of a related species, and form viable hybrids without human intervention.

Trial In-charge: The technical person designated by the Permitted 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 Regulatory Authorities. The Trial-in-Charge must, at a minimum, be an agriculture graduate.

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

Trial site location: The geographic location of a confined trial site *e.g.*, village, address and plot number.

Volunteers: Self-sown plants of the same species as the regulated plant that may germinate and grow on the trial site and/or within the isolation distance.

4 TERMS OF REFERENCE FOR MONITORING TEAMS

Monitoring teams may be constituted by RCGM/GEAC or any of the agencies delegated with authority by GEAC to undertake monitoring of confined field trial sites, or storage facilities, for the purpose of ascertaining compliance with the terms and conditions of authorization. These bodies may include the MEC, SBCCs, DLCs, and monitoring teams of state agricultural universities (SAUs). Individuals included in monitoring teams will be issued official letters identifying them as Members of the team for monitoring confined field trials or related activities. A copy of this letter will also be sent to the Permitted Party and these credentials must be available for presentation to the Trial In-charge, or Facility In-charge, during the site visit.

The following terms of reference shall apply to all members of monitoring teams.

4.1 Ethical Conduct

Trust, integrity, confidentiality and discretion are essential to monitoring activities and all members of monitoring teams shall conduct themselves in a professional and ethical manner. All information and documents, including working drafts and any reports, shall be considered confidential. The person heading the monitoring team or its members shall not release any information or documents to any third party without the prior written permission of the Regulatory Authorities.

4.2 Fair Presentation

The findings, conclusions and reports of monitoring teams will truthfully and accurately reflect the monitoring activities. Significant obstacles encountered during site visits and unresolved diverging opinions between the monitoring team and the Permitted Party will be recorded in the final report.

4.3 Due Professional Care

Monitoring teams will exercise care in accordance with the importance of the task they perform and the confidence placed in them by the Regulatory Authority. Having the necessary competence is a prerequisite for participation as a monitoring team member and the head of the monitoring team will be responsible for ensuring that all individuals designated as monitoring team members have necessary professional expertise.

4.4 Independence

Members of the monitoring teams should be independent of the activity being inspected and free from bias and conflict of interest. Team members must maintain an objective state of mind throughout the monitoring process to ensure that the findings and conclusions will be based only on the observations during their visit.

4.5 Evidence-based Approach

Reports of monitoring teams, upon which conclusions and regulatory actions may be based, must be verifiable. Such evidence may include photographs of trial site conditions, measurements of trial site dimensions and isolation distances, samples of documents and/or records, and first-hand interviews with technical personnel.

5 PROCEDURES FOR MONITORING TEAMS

The monitoring procedures are intensive and comprise the following:

1. **Preparation for the site visit:** This section outlines requirements for planning for a site visit and is applicable to all types of monitoring activities.
2. **Documentation inspection:** This outlines the kind of documents to be inspected in accordance with DBT's Standard Operating Procedures for Confined Field Trials of Genetically Engineered Plants.
3. **Storage facility monitoring:** This outlines the procedures to be followed for monitoring storage facilities, which may be located at the trial site and/or at a laboratory, greenhouse or other facility.
4. **Transport, storage and labelling:** Monitoring related to transport and/or storage. For identification purposes this is considered separately from facility inspection as these activities may be undertaken separately.
5. **Field trial monitoring during the growing period:** The requirements for this type of monitoring are divided into site location monitoring and monitoring for reproductive isolation.
6. **Termination, harvest and disposition:** The procedures entailing activities following termination or harvest of a trial and disposition of regulated genetically engineered plant material.
7. **Post-harvest site monitoring:** The procedures for monitoring trial sites during the period that mandated post-harvest land use restrictions are in effect.

5.1 Preparation For The Site Visit

Generally, visits by monitoring teams should be arranged in advance through communication with the Permitted Party, Trial In-charge or Facility In-charge. Prior to conducting any assessment, the members of the monitoring team should review and understand the following:

1. The Guidelines for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India;
2. Standard Operating Procedures or performance standards implemented during conduct of the field trial;
3. Terms and conditions of authorization attached to the letter of permit; and
4. Any applicable prior monitoring reports.

The following general requirements also apply:

1. In addition to material for recording observations (*i.e.* checklists and/or monitoring forms), accessories such as a measuring tape etc. may be required depending on the audit activity.
2. In the case of monitoring of confined field trial sites, monitoring teams will have a copy of the confined field trial map which clearly shows the following;

a. Trial-in-Charge's name and contact details.

b. Permit number from the Regulatory Authority.

c. Legal or descriptive land location (name of the village, taluka, district, state.)

d. Accurate distances to physical landmarks or surrounding landmarks such as telephone poles, fences, alleys, roads, or steel poles.

e. Total area planted with the regulated material, including negative controls and any border or guard rows when used (hectares or square meters).

f. Label all fields within the isolation area by the common name of the crop.

g. Indicate any fields of same/related crops that fall within, or border on, the isolation area.

h. Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, garden, orchard, forests, and woodlots, hedgerows), wherever reasonable.

i. Planting date.

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

3. After the Regulatory Authority has requested monitoring, the leader of the monitoring team or his authorized representative will contact the Permitted Party, or Trial In-charge, or Facility In-charge as appropriate, to schedule a site visit. If the Permitted Party, or its designate, has requested for the inspection, the monitoring teams will receive instructions from the Regulatory Authority. Follow-up monitoring to ascertain implementation of recommendations and/or corrective actions arising from a previous site visit may not require approval from the Regulatory Authority.

4. Prompt and accurate reporting by the monitoring teams is required to enable the Regulatory Authority to respond without delay to cases of non-compliance or violations. For cases that require immediate attention (*i.e.*, situations of actual or imminent accidental release of regulated plant material), the head of monitoring team will notify Regulatory Authorities immediately by telephone and positively within 24 hours in writing. Regulatory Authorities will advise the monitoring team on the appropriate course of remedial action. Upon receipt of instructions from Regulatory Authorities, the same would be communicated both verbally and in writing within 24 hours to the Trial In-charge (or Facility In-charge) and the Permitted Party by the monitoring team leader.

5. Monitoring of a confined field trial does not replace other monitoring activities or assessments of agronomic performance, nor does it exempt the plant material from meeting other phytosanitary and quality requirements under the relevant laws and rules.

5.2 Documentation Inspection

A review of required compliance documentation may be scheduled as a separate activity, but in practice it is often combined with either a trial site assessment or a storage facility inspection. The purpose of this inspection is to verify whether 1) copies of any relevant standard operating procedures are available and current; 2) all required forms and reports have been completed; and 3) copies of any mandatory notifications (*e.g.*, planting information submission, harvest information submission, accidental release information) have been transmitted to the Permitted Party or Regulatory Authority, as appropriate. The monitoring team will interact with the Facility In-charge or Trial In-charge in addition to perusal and inspection of the records. Compliance documentation that should be available for review may include:

1. Letter of permit authorizing conduct of the confined field trial;

2. Transport documentation (Record of Transport) for shipments of regulated plant material to, and between, field trial sites and contained facilities;

3. Storage facility documentation (Record of Storage; Record of Storage Inspection);
4. Current season documentation (Record of Planting; Record of Spatial Isolation and/or records for other methods of reproductive isolation);
5. Trial harvest and/or termination documentation (Record of Harvest/Termination and Disposition);
6. Post-harvest management documentation (Record of Post-Harvest Inspection); and
7. Any records related to compliance or corrective actions (Record of Corrective Action).

5.3 Storage Facility Inspection

Regulated plant material may be stored either at the trial site (*e.g.*, before planting or after harvest) or at fixed facilities, such as laboratories or greenhouses. In either case, the inspection should verify that storage facilities meet the minimum physical requirements stipulated in any applicable regulations, guidelines or SOPs, and that material management and monitoring processes are in place and being followed. The inspection should confirm that the following requirements have been met:

1. Regulated plant material is appropriately labelled and stored separately from any conventional seed or plant material in a fully enclosed, lockable space (*e.g.*, boxes, almirahs, cabinets, closet etc);
2. Access to storage areas is limited to authorized personnel and there must be evidence of some active access control system;
3. Areas or units designated for storage of regulated plant material must be cleaned prior to, and immediately following, the period of storage, and there should be records documenting these activities;
4. The storage area is clearly marked as containing regulated plant material, and used exclusively for that purpose;
5. All regulated plant material in storage is recorded on an inventory record, which also records all additions to, or removals from storage; and
6. Storage facilities be checked regularly to ensure they are secure, free of any waste or debris, and that material packaging or labelling has not been compromised, and this activity should be documented on records of storage inspection completed at least once every four weeks.

5.4 Field Trial Site Inspections

While monitoring of the trial site may occur at any time, the most useful times from a risk management perspective may include:

- **Prior to authorization –** to verify the physical surroundings and whether there are any circumstances that may be of special concern (*e.g.*, proximity of protected habitats and/or endangered species, proximity of cultivated fields of the same plant species; ownership and/or control of the trial site and surrounding isolation area);
- **During planting –** to verify material management procedures, cleaning of any equipment or implements used for planting, and disposition (*e.g.*, destruction or transport back to storage facility) of any remaining plant material;
- **During the period of crop flowering and prior to seed set –** this is the most critical time to verify if a method of reproductive isolation has been properly implemented, if appropriate monitoring activities are being carried out and documented, and if there are any conditions likely to result in a breach of reproductive isolation;
- **During harvest or trial termination –** to verify cleaning of any equipment or implements used for harvest or trial termination, the disposition of any harvested materials, and the destruction of any residual plant

material remaining on the trial site (*e.g.*, burning, chemical treatment, deep burial, soil incorporation); and

- **During the post-harvest period –** to verify if the area under postharvest restrictions is free of prohibited plants and if appropriate monitoring activities are being performed and documented.

  Specific considerations for monitoring teams conducted during different phases of confined field trial performance are briefly discussed below.

5.4.1 Site Location

- All four corners of each trial site must be clearly marked with physical landmarks suitable to permit identification of the trial site during both the current growing season and during any period of mandated post-harvest land use restriction.
- Confirm that the physical location of the trial site is actually the site identified on the map.

5.4.2 Reproductive Isolation

Regulated genetically engineered plants in the confined field trial must be reproductively isolated from any neighbouring sexually compatible plants by the isolation method described in the trial protocol and stipulated under the terms and conditions of authorization. A single field trial **site** must be reproductively isolated in its entirety by no less than one continuous method of reproductive isolation.

Spatial Isolation:

Spatial isolation is the standard method used for ensuring reproductive isolation of plants in the confined field trial. All plants in the trial (*e.g.*, regulated genetically engineered plants and any non-regulated plants used as checks or controls or in border rows) must be separated from other related species by the minimum isolation distance established by RCGM and indicated in the terms and conditions of authorization. Site inspections should confirm the following requirements related to spatial isolation:

- The spatial isolation distance must be of the required *distance* for the plant species undergoing trial, and it must be continuous and completely enclose the confined trial;
- The spatial isolation distance should be free of any prohibited plants. If prohibited plants are present, they must be removed prior to flowering otherwise this will be treated as a breach of reproductive isolation; and
- Records of monitoring of the spatial isolation distance should be available for review by the monitoring teams. These records should confirm that monitoring for prohibited plants within the isolation distance was performed at the required intervals and they should detail the occurrence and disposition (destruction by approved methods) of any prohibited plants found during routine monitoring.

5.4.3 Termination, Harvest and Disposition

At the termination of the confined field trial, either at harvest or for any reason prior to harvest, site visits should confirm that the following requirements have been met:

- All equipment and tools used to harvest the trial site must be cleaned and free of plant material before entering the trial site;
- Following harvest, all equipment and tools used must be cleaned on the trial site prior to removal in order to eliminate the unintended transport of regulated material from the trial site. Acceptable methods of cleaning include hand cleaning, compressed air, vacuuming of remaining seed, and high-pressure water. Any plant material recovered must be rendered non-viable by burning or burial on the trial site;
- All plant material harvested from a trial site and retained for future use must be transported from the trial site in approved, appropriately labelled containers, and in accordance with the SOP for the Transport of Regulated Genetically Engineered Plant Material. No harvested material may be retained without prior authorization by the Regulatory Authority; and,

- Records of harvest/termination should be available for review by the monitoring team. These records should detail the disposition of all harvested plant material, the cleaning of all equipment and tools used during harvest/termination, and the destruction (by approved methods) of all residual plant material on the trial site including any plant material from border rows.

5.4.4 Post-Harvest Period

All confined field trial sites are subject to a mandatory period of post-harvest land use restriction and the duration of this period is crop-specific and determined by the RCGM/GEAC, and stipulated in the terms and conditions of authorization. Site inspections during the post-harvest period should confirm that the following requirements have been met:

- The monitoring team should confirm whether post-harvest land use restrictions apply only to the trial site proper, or if they also include the spatial isolation distance (as would be the case in the event of a breach of reproductive isolation during the prior growing season).
- The field trial site should be marked according to the trial protocol. The four corners of each trial site must be maintained with physical landmarks suitable to permit identification of the trial site during the mandated period of post-harvest land use restriction (*e.g.* fence post, PVC piping).
- During the entire post-harvest period, the land under post-harvest restrictions must be maintained free of prohibited plants. If prohibited plants are present, they must be removed prior to flowering.
- Records of monitoring of the post-harvest area should be available for review by the monitoring teams. These records should confirm that monitoring for prohibited plants within the post-harvest area was performed at the required intervals and they should detail the occurrence and disposition (destruction by approved methods) of any prohibited plants found during routine monitoring.

5.5 Completing The Monitoring Report

Upon completion of the facility and/or site visit, the monitoring team should have a closing meeting with the Permitted Party, Trial In-charge and/or Facility In-charge (as appropriate) to present the findings and conclusions so they are understood and acknowledged by the Permitted Party, Trial In-charge and/or Facility In-charge, and to agree, if appropriate, on any corrective actions that may be necessary to bring the confined field trial into full compliance. Minutes of the meeting, including records of attendance, should be noted in the monitoring report. Any differences of opinion regarding the inspection findings and/or conclusions between the monitoring teams and the Trial In-charge should be discussed and if possible resolved. If these are irresolvable, the divergent opinions should be recorded.

The monitoring team should complete the monitoring report and send copies of this report to the Regulatory Authority, the monitoring body (*e.g.*, MEC, SBCC, DLC) and the Permitted Party.

In the event of any compliance infraction discovered during the monitoring process that has resulted in an accidental release of regulated plant material, the monitoring team will notify Regulatory Authorities immediately by telephone and positively within 24 hours in writing. Regulatory Authorities will advise the monitoring team on the appropriate course of remedial action. Upon receipt of instructions from Regulatory Authorities, the same would be communicated both verbally and in writing within 24 hours to the Permitted Party, Trial In-charge or Facility In-charge by the monitoring team leader. A Record of Corrective Action, detailing the incident and the corrective action taken, is to be initiated by the Permitted Party, Trial In-charge or Facility In-charge. In the event of any nonconformities requiring immediate corrective action, the monitoring team leader should arrange a time for a follow-up site visit to confirm that the necessary actions have been implemented.

6 PROFORMA CONFINED FIELD TRIAL INSPECTION REPORT

INSTRUCTIONS

Parts A - H of this report should be completed for each site location. Additional copies of Part B of this form can be completed in cases where there is more than a single confined field trial site at a given trial site location.

A copy of this completed report should be submitted to the **Regulatory Authority** (RCGM/GEAC), the relevant monitoring body (MEC, SBCC, DLC), and the Permitted Party **WITHIN FIVE (5) DAYS** of the site visit.

In the event of any **compliance infraction** discovered during a site visit that results in an accidental release of regulated genetically engineered plant material, Regulatory Authorities will be notified immediately by telephone and in writing within 24 hours. Regulatory Authorities will advise on the necessary corrective actions to be implemented and a **Record of Corrective Action**, detailing the incident and the corrective action taken, is to be initiated by the Permitted Part, Trial In-Charge or Facility In-Charge and provided to the Monitoring Team. Upon completion of the corrective action, copies of the **Record of Corrective Action** will be forwarded to the **Regulatory Authority** and the Permitted Party.

PART A: GENERAL INFORMATION PERMITTED PARTY		
Last Name	First Name	MI
Company/Organization	Contact	
Telephone	Facsimile	Electronic Mail
Address		

TRIAL IN-CHARGE OR FACILITY IN-CHARGE		
Last Name	First Name	MI
Company/Organization	Contact	
Telephone	Facsimile	Electronic Mail
Address		

PART B: TRIAL SITE INFORMATION

Legal or Descriptive Land Location of Trial Site			
Crop Planted at Trial Site ☐ Cotton ☐ BrinjaL ☐ Other (list) Date of sowing _____			
Timing of the Inspection and Stage of Crop Development ☐ At planting ☐ Vegetative, pre-flowering ☐ Flowering ☐ After flowering ☐ At harvest ☐ Post-harvest Copies of inspection reports at various stages be made available to monitoring teams for all subsequent inspections.			
1.	Are physical landmarks (PVC piping, fence post, etc.) at located each corner of the trial site?	☐ Yes	☐ No
2.	Do measurements of the trial size match information on the trial site map?	☐ Yes	☐ No
3.	Distance to the nearest cultivated fields of the same plant speciesas the plants in the confined field trial:	_____ Meters	
4.	Distance to the nearest cultivated crop of any kind:	_____ Meters	
5.	Is the trial site, including the spatial isolation distance, under the control of the Trial In-Charge and/or Permitted Party?	☐ Yes	☐ No
6.	Is there a **Notice Board** at the trial site indicating the purpose and duration of the confined field trials conducted at the trial site and the authorization under which the confined field trials were approved?	☐ Yes	☐ No
7.	Is there a bound log book including the name, address and affiliation of all personnel who have entered the trial site?	☐ Yes	☐ No
8.	Was planting/harvesting equipment/implements cleaned in the appropriate manner prior to, and after, use on the trial site?	☐ Yes	☐ No
9.	Event(s) planted at the trial site (attach list if necessary)		

PART C: REPRODUCTIVE ISOLATION

Method of Reproductive Isolation ☐ Spatial Isolation ☐ Other (list)				
1.	Do measurements confirm that the trial site has the appropriate isolation distance? (cotton: 50 m; brinjal: 300 m; etc)	☐ Yes	☐ No	
2.	Is the isolation distance free of any **prohibited plants**? (*e.g.*, plants of any species sexually compatible with the regulated plants)	☐ Yes	☐ No	
3.	Is there a written **Record of Spatial Isolation**?	☐ Yes	☐ No	
4.	Does the Record of Spatial Isolation confirm that monitoring of the isolation distance has been performed at the required intervals? (see Letter of Permit from Regulatory Authority)	☐ Yes	☐ No	
5.	Were growth stages of the trial plants, including any prohibited plants observed in the isolation distance, recorded?	☐ Yes	☐ No	
6.	If records indicate that prohibited plants have been removed from the isolation distance during routine monitoring, do they also indicate themethod of destruction, and was this appropriate?	☐ Yes	☐ No	☐ NA
7.	Have there been any prior instances of non-compliance during the current growing season?	☐ Yes	☐ No	
8.	If the answer to C.7 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No	☐ NA

PART D: STORAGE OF REGULATED PLANT MATERIAL

ONLY COMPLETE IF REGULATED PLANT MATERIAL IS IN STORAGE AT THIS LOCATION ☐ Regulated plant material is stored at this location				
1.	Is the regulated plant material stored separately from conventional seeds in a fully enclosed, lockable space? (*e.g.*, boxes, almirahs, cabinets, closet etc)	☐ Yes	☐ No	
2.	Is the storage area clearly labelled as containing regulated plant material and is it used exclusively for that purpose?	☐ Yes	☐ No	
3.	If multiple regulated articles are in storage, are they within separate, sealed containers?	☐ Yes	☐ No	
4.	Is the storage area clean and free of any waste or debris?	☐ Yes	☐ No	
5.	Is there a **Record of Inventory** that details all of the regulated plant material in storage and any additions to, or removals from, storage?	☐ Yes	☐ No	
6.	Based on a sampling of entries from the **Record of Inventory**, is there a correlation between the physical presence of an inventory item andthe **Record of Inventory**?	☐ Yes	☐ No	
7.	Is there a **Record of Storage Inspection**?	☐ Yes	☐ No	
8.	If it exists, does the **Record of Storage Inspection** confirm that the storage location has been inspected at least once per month?	☐ Yes	☐ No	
9.	Have there been any prior instances of non-compliance during the current year?	☐ Yes	☐ No	
10.	If the answer to D.9 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No	☐ NA

PART E: POST-HARVEST RESTRICTIONS

ONLY COMPLETE IF THIS IS A PRIOR-YEAR TRIAL SITE UNDER POST-HARVEST RESTRICTIONS

☐ Prior-year trial site(s) under post-harvest land use restrictions at this location

1.	Is the post-harvest trial site clearly marked with physical landmarks at each corner?	☐ Yes	☐ No	
2.	Does the post-harvest area under restriction include only the trial site proper? (If not, it also includes the spatial isolation distance)	☐ Yes	☐ No	
3.	Does the Trial In-charge (or Permitted Party) have control of the entire area under post-harvest land use restrictions?	☐ Yes	☐ No	
4.	Is the post-harvest trial site being managed in a way that enables the identification of volunteers, or other prohibited plants, and theirdestruction?	☐ Yes	☐ No	
5.	Is there a **Record of Post-Harvest Monitoring**?	☐ Yes	☐ No	
6.	If it exists, does the **Record of Post-Harvest Monitoring** confirm that the post-harvest trial site has been monitored at least once every four weeks for the presence of prohibited plants?	☐ Yes	☐ No	
7.	If records indicate that prohibited plants have been removed from the post-harvest site during routine monitoring, do they also indicate themethod of destruction, and was this appropriate?	☐ Yes	☐ No	☐ NA
8.	Have there been any prior instances of non-compliance during the current post-harvest period?	☐ Yes	☐ No	
9.	If the answer to E.8 was YES, was a **Record of Corrective Action** initiated and were the necessary actions implemented?	☐ Yes	☐ No	☐ NA

PART F: DOCUMENTATION AND RECORD KEEPING

1.	Are copies of SOPs and related records readily accessible and up-to-date for this trial site location?	☐ Yes	☐ No
2.	Is a copy of the letter of permit for all events planted at this trial location readily accessible?	☐ Yes	☐ No
3.	Are the **Record of Transport** documents complete?	☐ Yes	☐ No
4.	Has a **Record of Planting** and a trial site map been completed?	☐ Yes	☐ No
5.	Have the **Record of Planting** and trial site map been forwarded to the **Regulatory Authority**?	☐ Yes	☐ No

PART G: ADDITIONAL COMMENTS

Summarize :-

- any discussions with the Trial In-charge or other Personnel,

- feedback on the SOPs maintened

- any recommended corrective actions and

- any other pertinent details/ observations.

PART H: COMPLIANCE ASSESSMENT

PLEASE INDICATE ONE OF THE FOLLOWING CATEGORIES OF INSPECTION STATUS

☐ **No compliance deviations, all documentation in order.**

Field trial conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants and the Compliance Documentation was up-to-date.

- No actions required

☐ **No compliance deviations, but with documentation deficiencies.**

Field trial conducted in accordance with SOPs for Confined Field Trials of Regulated Genetically Engineered Plants, **BUT the Compliance Documentation was not up-to-date**.

- Instruct the Trial In-charge on actions needed to update the Compliance Documentation or other records
- Make a note to verify any corrective actions during the next site inspection

☐ **Compliance deviations, but no documentation deficiencies.**

Field trial **NOT conducted in accordance with SOPs** for Confined Field Trials of Regulated Genetically Engineered Plants BUT the Compliance Documentation was up-to-date.· Request a

- **Record of Corrective Action** be initiated and consult with the Trial In-charge on the appropriate corrective actions to be taken. In the event of any accidental release, notify the **Regulatory Authority** immediately by telephone and in writing within 24 hours.
- Schedule a follow-up inspection as soon as practical to verify that appropriate corrective actions have been implemented.
- If the nature of the infraction is such that destruction of the trial site is warranted, consult with the **Regulatory Authority** prior to instigating this action

☐ **Compliance deviations AND documentation deficiencies.**

Field trial **NOT conducted in accordance with SOPs** for Confined Field Trials of Regulated Genetically Engineered Plants **AND the Compliance Documentation was not up-to-date**.

- Request a **Record of Corrective Action** be initiated and consult with the Trial In-charge on the appropriate corrective actions to be taken. In the event of any accidental release, notify the **Regulatory Authority** immediately by telephone and in writing within 24 hours.
- Instruct the Trial In-charge on actions needed to update the Compliance Documentation or other records.
- Schedule a follow-up inspection as soon as practical to verify that appropriate corrective actions have been implemented.
- If the nature of the infraction is such that destruction of the trial site is warranted, consult with the **Regulatory Authority** prior to instigating this action

PART I: Monitoring Team VERIFICATION

This activity has been carried out to assess compliance with the Guidelines for the Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India and related Standard Operating Procedures. By my signature, below, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief.

Names and Designation of Monitoring Team — Signature and date

LEADER : _____

Members : 1. _____

2. _____

3. _____

4. _____

5. _____

COMPREHENSIVE GLOSSARY OF TERMS

COMPREHENSIVE GLOSSARY OF TERMS

Accidental release: Any unintended release of regulated plant material into the environment, food and/or feed chains. For the purposes of these Guidelines, any breach of the authorized terms and conditions for reproductive isolation of the confined trial site shall be considered an accidental release. Accidental release also includes the spillage, theft, or encroachment by unauthorized persons of regulated GE plant material during transportation, storage within a contained facility, or during any other activity associated with the conduct of a confined field trial. Any accidental release shall be subject to risk assessment, and any necessary corrective actions shall be at the cost of the applicant or permitted party.

Anthesis: The time of flowering or pollination. Anthesis is complete when flowering or pollination is complete.

Applicant: The Applicant must be a permanent resident of India or must designate an Authorized Signatory (AS) who is a permanent resident of India. Where an AS is used, there must be a formal, legal agreement indicating the AS is acting on behalf of the Applicant and both under the jurisdiction of any Court of Law of India. A copy of this agreement must be submitted to the Regulatory Authorities along with the confined field trial application. The Applicant need not be the breeder/developer or owner of the regulated plant, in which case a signed statement is required from the breeder/developer or owner authorizing representation by the Applicant or the designated AS. All correspondence with respect to the application for a confined field trial, including the notification of authorization, will be addressed to the Applicant, or when appropriate, the AS.

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. Applicants must use the proforma attached as Annexure 1 to the Guidelines for Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India.

Authorization: A letter of intent or permit issued by the regulatory authority (RCGM or GEAC) to conduct any research experiment on GE plants under specified terms and conditions.

Breach: Any contravention or violation of any term and/or condition of authorization of a confined field trial will be considered a breach under the Guidelines for Conduct of Confined Field Trials of Regulated Genetically Engineered Plants in India.

Confined Field Trial: A confined field trial is a field experiment of a regulated GE plant under terms and conditions that are intended to mitigate the establishment and spread of the plant. A single confined field trial may be comprised of one or more varieties/hybrids of a single event of a single plant species that are subject to the same terms and conditions of confinement which include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. The field trials are categorized into two types: Biosafety Research Level I and Biosafety Research Level II trials.

Construct: An engineered DNA fragment containing, but not limited to, the DNA sequences to be integrated into the genome of the target plant.

DBT: Department of Biotechnology.

DLC: District Level Committee.

Early termination: Any termination of a confined field trial before the anticipated completion date.

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.

Facility In-Charge: The person designated by the Permitted Party as responsible for the storage (before or at planting, during planting and after harvest) of regulated, genetically engineered plant material.

Field trial: The planting of one or more regulated events in a single experimental plot.

GEAC: Genetic Engineering Approval Committee.

Genetic engineering: The technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material (Rules, 1989).

Government: Government means Central or State Government and Government Agencies that are associated organizations/bodies with Central or State Government

IBSC: Institutional Biosafety Committee

Isolation distance: A mandated distance used to spatially separate a confined field trial from the nearest plant of the same or any sexually compatible species. Minimum spatial isolation distances vary depending on the reproductive biology of the plant species, and minimum distances for a number of plant species have been established by the RCGM.

MEC: Monitoring cum Evaluation Committee.

Methods of reproductive isolation: Means used to prevent movement or dissemination of regulated plant material by pollen or seed from the confined trial site (e.g., establishing an area around the perimeter of a trial site that is kept free of any prohibited plants for the period of the trial; terminating a confined field trial before the plants in the trial flower and release pollen).

Monitoring agencies: Includes Monitoring cum Evaluation Committee (MEC) set up by RCGM as per the Guidelines for research in transgenic plants, 1998, pre release monitoring teams set up by the state agricultural universities (SAUs) under the directions of RCGM/ GEAC/SBCC/DLC or any other persons/organizations nominated by RCGM/ GEAC for monitoring of confined field trials.

Packaging Material: The material used to secure regulated, genetically engineered seed or other propagable plant material for the purposes of transport and storage. Examples include polythene bags, seed envelope, cardboard box.

Permitted Party: The Applicant or designated AS will be considered the 'Permitted Party' for the purposes of authorization and is the person who shall accept responsibility for compliance with the terms and conditions of the permit. The 'Permitted Party' may designate a Trial-in-Charge, who will be responsible for ensuring compliance with the requirements of authorization as specified by the Regulatory Authority.

Physical landmarks: Landmarks used to identify or designate boundaries of a confined field trial site (e.g., telephone poles, fences, alleys or roads).

Plant material: Propagable material (e.g., seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagable material (e.g., leaves, devitalized material).

Post-harvest period: A period of time that follows the harvest or termination of a confined field trial when restrictions are imposed on the use of the trial site.

Primary container: The container into which regulated plant material is placed (e.g. sealed bag, envelope, polythene bags, cardboard box etc).

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.

Propagable: Any plant or plant part that can be used in the field to regenerate a whole plant under typical field conditions.

RCGM: Review Committee on Genetic Manipulation

Recipient: For the purpose of DBT's Standard Operating Procedure for Confined Field Trials of Genetically Engineered Plants: Transport, Storage, Management, Harvest or Termination and Post Harvest Management, the Recipient shall be the Permitted Party, Trial-in-Charge or Facility-in-Charge.

Regulated plant: Any plant produced through genetic engineering, including seed or propagable plant material derived from that plant, which has not been authorized by the Regulatory Authorities for commercial cultivation pursuant to the Rules, 1989 of the Environmental Protection Act, 1986.

Regulatory Authority: As regards confined field trials, RCGM is the regulatory authority responsible for authorizing Biosafety Research Level I trials and GEAC is the regulatory authority responsible for authorizing Biosafety Research Level II trials.

Reproductive isolation: Refers to the means used to prevent movement of plant material, particularly pollen, from a confined field trial site.

Rules, 1989: Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms, Genetically Engineered Organisms or Cells Rules, 1989 conferred by sections 6, 8 and 25 of the *Environmental (Protection) Act, 1986*.

SAU: State Agricultural University

SBCC: State Biotechnology Coordination Committee.

Secondary container: The container into which a primary container is placed.

Seed: Means any type of embryo or propagule capable of regeneration and giving rise to a plant of agriculture which is true to such type. The definition of the seed will be taken as per the rules applicable at that point of time.

Sexually compatible: Ability of a plant to cross-pollinate with other cultivated plants of the same species, or with wild plants of a related species, and form viable hybrids without human intervention.

Site map: Map of the trial site providing sufficient details on the dimensions, distances to physical landmarks, layout of the site etc. to allow regulatory officials/monitoring agencies to locate each field trial site during the planting season as well as during any required period of post harvest land use restriction.

Transformation: The process of incorporating DNA into an organism's genome. There are several methods to do this in plants. The most commonly used methods for plant transformation are *Agrobacterium*-mediated transformation and biolistic transformation.

Transport In-Charge: The person identified by the Permitted Party as being responsible for the transport of regulated plant material.

Trial In-Charge: The technical person designated by the Permitted 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 Regulatory Authorities. 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 Regulatory Authorities.

Trial site: The area where one or more confined field trials of the same plant species may be grown. For example, three confined field trials of cotton surrounded by a shared 50 m isolation area would constitute a single trial site.

Trial site location: The geographic location of a confined trial site e.g., village, address and plot number.

Volunteers: Self-sown plants of the same species as the regulated plant that may germinate and grow on the trial site and/or within the isolation distance.