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:

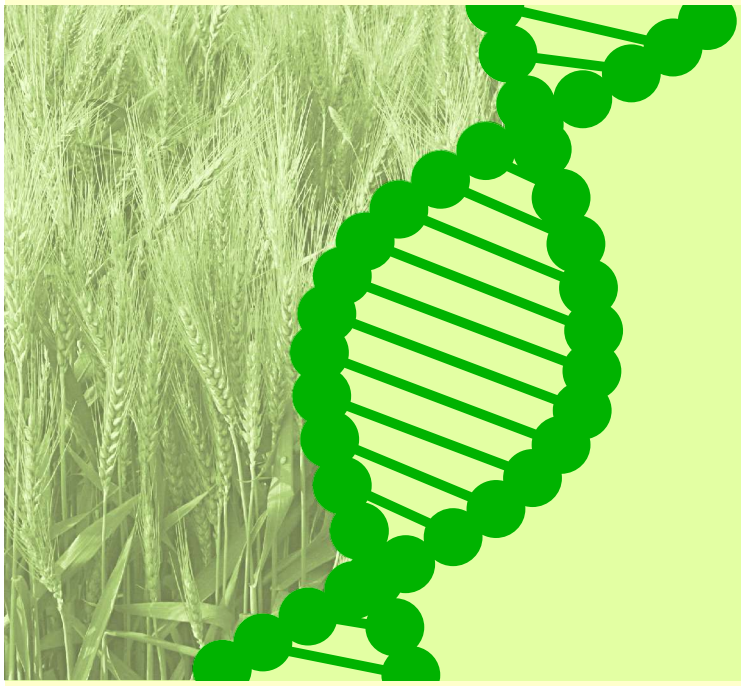
1. The Permitted Party shall ensure that genetically engineered seed and/or plant material for planting is transported in clearly identified, secure containers and kept separate from other seed and/or plant material. All packing material, shipping containers, and any other material accompanying the genetically 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.