



APPLICATION FOR CONFINED FIELD TRIAL

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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

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, 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.

(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-living¹ 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
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Donor organism source of toxins or allergens? yes no **Protein expressed** yes no

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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
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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
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Feature type CD - coding AS - antisense EH - ehancer PR - promoter TR - termination/polyadenylation
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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
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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, if known ($\mu\text{g/g}$) _____

Is the protein a known human allergen? yes no 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, if known ($\mu\text{g/g}$) _____

Is the protein a known human allergen? yes no 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, if known ($\mu\text{g/g}$) _____

Is the protein a known human allergen? yes no 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, if known ($\mu\text{g/g}$) _____

Is the protein a known human allergen? yes no Is the protein known to be toxic to humans or non-target organisms? yes no
If YES, provide details. 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, if known ($\mu\text{g/g}$) _____

Is the protein a known human allergen? yes no Is the protein known to be toxic to humans or non-target organisms? yes no
If YES, provide details. 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, yes no or germination rate?

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 m²) _____

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.
