Form D3 - Event Selection APPLICATION TO UNDERTAKE CONFINED FIELD TRIAL AND TO UNDERTAKE SAFETY STUDIES OF GENETICALLY ENGINEERED CROPS/ PLANTS FOR AGRICULTURAL AND ENVIRONMENTAL USE

Instructions to follow

☐ Already Selected Event

Applicant to tick this box if the event is already selected from laboratory studies or approved elsewhere outside India.

- PART 1
- PART 2
- PART 3
- PART 4
- PART 5
- PART 8

A. Applicant Details :

Organization Name :

Name of Applicant :

Designation :

Address/Line-1 :

Address/Line-2 :

State / UT :

District :

Village / Town / City :

Pin Code :

Office Phone Number :

With STD Code

Mobile No :

Email :

B. Application Type :

Event Selection (ES)

C. Application For :

D1. Product Code :

Choose/ generate the CODE, which explicitly conveys the essence of the proposed work. Kindly note that the same code might be used for generation of future references.

D2. Status of the project :

Revised Submission New Submission

E. Chronology of approval(s) accorded so far by the IBSC for the event(s) under investigation :

- Mention the date(s) of IBSC meeting wherein various considerations pertaining to the event(s) under investigation were deliberated and approved.
- Enclose color photocopy(ies) of the minutes of the relevant IBSC meeting(s)

Upload

please upload only .pdf,.doc,.png,.gif and .docx file.

F. Chronology of approval(s) accorded so far by the RCGM for the event(s) under investigation:

- Mention the date of permission(s) issued previously by the GEAC for the event(s) under investigation.
- Enclose color photocopy(ies) of permit(s) issued earlier

Upload

please upload only .pdf,.doc,.png,.gif and .docx file.

G. Chronology of approval(s) accorded so far by the GEAC for the event(s) under investigation:

- Mention the date of permission(s) issued previously by the GEAC for the event(s) under investigation.
- Enclose color photocopy(ies) of permit(s) issued earlier

Upload

please upload only .pdf,.doc,.png,.gif and .docx file.

H. background about the event(s) under investigation :

H.1: Event(s) Identity :

Write self-explanatory name of the product

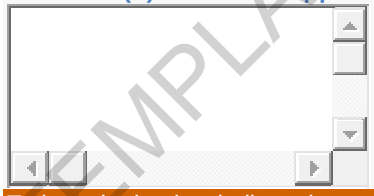
H.2: Country of Origin :

In Case,plant material to be used in the confined field trial is imported,
provide NBPGR import permit number with date of import/relevant approval letter.

Upload

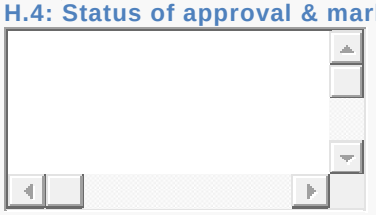
please upload only .pdf,.doc,.png,.gif and .docx file.

H.3: Trait(s) for which applied for :



To be submitted as bullet points

H.4: Status of approval & marketing history in country of origin and worldwide :



PART 2

I. Unmodified plant species

Latin Name	Common Name	Biology Document for the Plant Species
		Upload Upload NMT 5 MB

I.1: Whether the unmodified plant species has an extended history of safe use in Food, Feed, and Agriculture?

Provide details.

Yes No

I.2: Is the plant species considered to be weedy or naturally invasive?

If yes, list any locations below

Yes No

I.3: Are there any member(s) of the family of plant species considered to be weedy or naturally invasive in India?

If yes, list any locations below

Yes No

I.4: Are there sexually compatible wild relatives of the plant species Globally?

If yes, list any locations below

Yes No

I.4.1 Are there significant free-living populations of the plant species in India?

.4.1 Are there significant free-living populations of the plant species in India?

If yes, list name of species and locations below.
Free-living plant populations are those which are able to survive,
without direct human assistance,over the long term in competition with the native flora.

Yes No

I.4.2 Are there sexually compatible wild relatives of the plant species in the State (s) where trial(s) proposed to be conducted?

If yes, list name of species and locations below

Yes No

I.5: Known centre(s) of origin of plant species

I.6: Known centre(s) of genetic diversity

I.7: Pollen Behaviour

Details of pollen viability and physiology	Mechanism of pollen dispersal		Mode of Pollination			
			Mechanism of Self Pollination		Mechanism of Cross pollination	
	Specify insect (s) species their range and distribution pattern, If chosen 'Insect' from the list	Specify the mechanism, If chosen 'Other' from the list		Specify the Self Pollination mechanism, If chosen 'Other' from the list		Describe Briefly

I.8: Seed Physiology

Mechanism(s) of natural seed dispersal	Seed dormancy (including tubers)

	Specify the mechanisms of seed dispersal, If chosen 'other' from the list		Specify seed dormancy, If chosen 'other' from the list
--Select--			

I.9: Is the plant species known to be allelopathic?

If yes, provide further details

Yes No

I.10: Is the plant species known to be a source of substances toxic to humans or animals?

If YES, name the compounds, the levels that induce toxicity, and the affected species.

Yes No

I.11: Is the plant species known to be a source of human allergens?

If yes, provide details thereof.

Yes No

I.12 Details of anti-nutrients and secondary metabolites inherently present in the recipient plant which may adversely affect human/animal health.

PART 3

J. Information on the genetically engineered plant

J.1 CATEGORY OF GENETIC MODIFICATION		
	Specify the category, If chosen 'Other' from the list	Specify seed dormancy, If chosen 'other' from the list
--Select--		

J.2 NUMBER OF EVENTS TO BE EVALUATED	J.3 IDENTIFICATION CODE(S) OR EVENT(S) NAME FOR EACH GE EVENT INCLUDED IN THE APPLICATION	J.4 THE EVENT(S) ARE		J.5 GENERATION OF THE EVENT(S)	J.6 PEDIGREE INFORMATION OF EVENT(S)
		--Select--	Stacked event(s) generated through		Upload please upload only .pdf,.doc,.png,.gif and .docx file.

				Feature of Molecular Stack	The identification code of parent event(s)		

J.7: Phenotype

J.7.1 Whether the genetic modification leads to change in the plant phenotype compared to the unmodified plants of the same genotype?

If Yes, describe the effects of genetic engineering of the plant phenotype (list the changes Such as difference in appearance of the plant like increased tillering or branching).

Yes No

J.7.1.1 If it is intended modification explain the mechanism of action:

J.8: Previous confined field trials

J.8.1 Whether the event(s) tested in India previously?

If YES, enter most recent trial authorization along with outcome of the trial.

Yes No

J.8.2 Event(s) previously approved for unconfined (general or commercial) release in other countries?

If YES, list countries and year of approval.

Yes No

J.9: MODIFICATION METHOD

	Specify the method, If chosen 'Other' from the list	Describe the transformation method(s) followed
--Select--		

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J.10: Selection agent(S) used to regenerate transformed cell / plant

	Specify the selection agent, If chosen 'Other' from the list	Provide more details of the selection agent
--Select--		

J.11: Introduced DNA

For multiple gene construct, add rows by clicking " ADD GENE CONSTRUCT " below.

J.11.1 Gene Constructs

	Gene Construct Name	Size of the Gene Construct (kb)	GenBank Accessio vector ba
--Select--			

J.11.1.1 Briefly describe changes introduced in the vector, if any

J.11.1.2 Mode of action of transgene(s)

J.11.1.3 Does the introduced DNA give rise to any infectious agent?

If Yes, provide details.

YES NO

J.11.1.4 Does the introduced DNA contain any sequences derived from Known human, animal or plant pathogens?

If Yes, provide details.

YES NO

J.12: Construct composition and expression

J.12.1 Gene Construct

J.12.1.1 Gene Cassettes

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.

J.12.1.1.1 Trait Category

--Select--

Cassette

J.12.1.1.2 Genetic Elements

Name	Feature Type	Only if chosen feature type is "OO-Other"	GenBank Accession Number	Starting Position (bp)	End Position (bp)	Size (kb)
	--Select--					

J.12.1.1.2a Whether any modification(s) incorporated in native DNA sequence of the genetic element?

If yes, provide details thereof.

YES NO

J.12.1.1.2b Whether the genetic element is coding for a polypeptide/ protein?

If yes, provide below mentioned information.

YES NO

J.12.1.1.2c Whether the genetic element is a promoter/ regulatory sequence?

If yes, choose relevant option from dropdown menu.

YES NO

J.12.1.1.2d Source Organism

Common Name	Genus & Species Name

J.12.1.1.2da Whether the source organism is a source of known toxin(s) and/ or allergen(s)?

if yes, provide details thereof.

YES NO

J.12.1.1.2db Whether the source organism has history of use in consumption?

If YES, provide details of the use (e.g, country, types of uses, tissues used, including any approved food use by regulatory authorities etc.)

YES NO

J.12.1.1.2dc Whether the protein(s) encoded by the introduced DNA known for any post-translational modification in donor organism?

if yes, provide details thereof.

YES NO

J.12.1.1.2e Whether the genetic element share homology with gene(s)/ regulatory sequence(s) of the host plant used for genetically engineering?

If YES, list below mentioned details (provided that DNA sequence of the homologous/ orthologous genetic element/ or genome of the host plant is known)

YES NO

J.12.1.1.3 RNA Expression

Provide information for each expressed RNA (mRNA, antisense RNA, miRNA, siRNA etc.) from the gene cassette.

J.12.1.1.3a RNA

Type of RNA Expressed	Provide relevant detail	Name of the Gene Transcribed	Size of the Expressed	Whether RNA Expression is	If the expression is other than the Constitutive, provide information whichever is relevant

	s, if, type of RNA expressed other than the mentioned list		RNA (base)					
					Specific Tissue(s)	Inducer(s)	Developmental Stage(s)	Other
--Select--				--Select--				

J.12.1.1.4 Protein Expression

Provide information for expressed protein product(s) from the gene cassette

J.12.1.1.4a Proteins

Sr. No.	Name of the Protein	Molecular weight (kDa) of the protein	Amino acid sequence of the expresses protein in FASTA format.	Whether Protein Expression is	If the expression is other than the Constitutive, provide information whichever is relevant			
					Specific Tissue(s)	Inducer(s)	Developmental Stage(s)	Other
				--Select--				

J.12.1.1.4ac Is the protein a known human allergen?

If yes, Provide details thereof.

YES NO

J.12.1.1.4ad Is the protein known to be toxic to humans or non-target organisms?

If yes, Provide details thereof.

YES NO

J.12.1.1.4ae Background information on history of use, allergenicity, and toxicity of the introduced transgene protein

J.12.1.1.4af Bioinformatics analysis of the expressed protein, to detect homology with allergens, anti nutrients and toxic proteins

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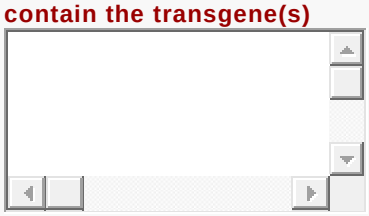
J.15: Unintended changes due to genetic modifications

J.15.1: Details of pleiotropic effects on the parent plant that may result from the expression of the transgene(s), or an insertion related mutation in the GM plant event(s), (e.g., disease susceptibility, effects on fertility, production, grain shedding) including the likelihood of any such event(s)

J.15.2: Details of any secondary genetic effects that is anticipated or may be anticipated

J.15.3: Details whether the genetic modification limits or eliminate any capacity to reproduce or transfer gene(s) to other organism, if any.

J.15.4: If the inserted gene construct(s)/trait(s) transferred to a related species, what advantages the recipient plant(s) are likely to have over members of the species that do not contain the transgene(s)



J.17: Intended on anticipated changes due to genetic modification.

J.17.1: Whether the genetic modification intended to alter plant weediness?

If YES, describe which parts/plants

( ) Yes (•) No

J.17.2: Whether the genetic modification intended to alter plant nutrient composition?

If yes, provide details thereof

( ) Yes (•) No

J.17.3: Whether the genetic modification intended to alter allelopathic characteristics of a plant?

If yes, provide details thereof

( ) Yes (•) No

J.17.4: Whether the genetic modification intended to alter seed dormancy, viability or germination rate?

If yes, provide details thereof

( ) Yes (•) No

J.17.5: Whether the genetic modification intended to alter pollen dispersal?

If yes, provide details thereof

( ) Yes (•) No

J.17.6: Whether the genetic modification intended to alter seed dispersal?

If yes, provide details thereof

( ) Yes (•) No

J.17.7: Whether the genetic modification intended to alter vegetative dispersal?

If yes, provide details thereof

( ) Yes (•) No

PART 4

K. Information on the trial site

K.1 Trial in charge

Name :

Designation :

Organization :

Address/Line-1 :

State / UT :

District :

Village / Town / City :

Pin Code :

Office Phone Number :

With STD Code

Mobile No :

Email :

K.2 Trial site

K.2.1 Applicant's site location code

K.2.2 No. of trials to be conducted at this location

K.2.3 Trial site/ plot size (ha or m^2)

Provide details of gross and net plot size

K.2.4 Provide Trial site location and GPS coordinates.

K.2.5 Details of ownership and agreement

Upload

please upload only .pdf,.doc,.png,.gif and .docx file.

K.2.6 Distance to nearest cultivated crop of the same species (m)

K.2.7 Distance to nearest commercial crop of any kind (m)

K.2.8 Is the isolation distance under the control of Trial-in Charge.?

Yes No

K.2.9 Whether the isolation distance is in conformity with the standards specified for certified seed production of the crop?

Yes No

K.2.10 Whether the trial site soil is suitable for cultivation of the crop proposed?

Yes No

- If yes, provide basic soil data (soil type, pH, EC, etc.)
- If No, provide reason(s) for proposing trial at this location

K.2.11 Whether the trial site falls in the location of hot spot areas of target pest/disease as per the previous information available?

Yes No

If No, provide reason(s) for proposing trial at this location

K.2.12 Whether the trial site is suitable for the crop proposed and intended trait as per the previous information available(e.g hot spot for biotic and abiotic stress traits)?.Provide details.

Yes No

K.3 Trial Layout Plan and Trial Protocol

K.3.1 Has a complete map of the trial site been enclosed?

Yes No

K.3.2 Have you attached the experimental design of the trial?

Yes No

K.4 Habitat

K.4.1 Is the trial site part of a managed ecosystem (i.e. agricultural land)?

Yes No

K.4.2 Is there an area of special ecological interest (e.g. biodiversity park, protected area, Sanctuary) near the trial site?

Yes No

K.5 Indigenous Species

K.5.1 Describe any sexually compatible wild or cultivated plant species that are in the vicinity of the trial site.

K.5.2 Are there any endangered or threatened species on or near the trial site?

Yes No

K.5.3 What mechanisms are in place to prevent local fauna from removing plant material from the trial site?

PART 5

L. The Trial Protocol

L.1 Important Dates

L.1.1 Anticipated planting date

L.1.2 Anticipated Flowering date

L.1.3 Anticipated harvest date

L.2 Study Description

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please upload only .pdf,.doc,.png,.gif and .docx file.

L.2.1 Purpose of the field trial

L.2.2 Experimental Design

Shall also include details of site characterization, soil physiochemical properties, crop management practices, imposition of treatments - care during sprays, soil applications of nutrients/ manure/ bio-inoculants, irrigation management, sampling, avoiding spray drifts, past weather data (if trial is for abiotic stresses), etc.

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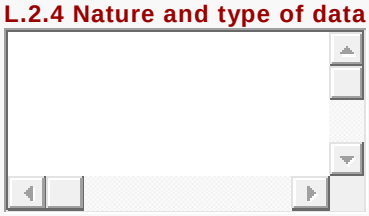
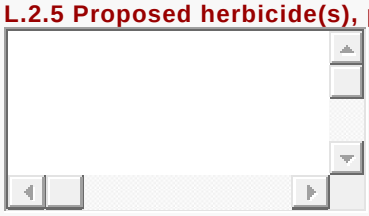
L.2.3 Number of trap rows and length

L.2.4 Nature and type of data to be collected



L.2.5 Proposed herbicide(s), pesticide(s) to be used



L.2.6 Elaborate statistics to be applied for trait efficacy and agronomic parameter.

L.2.7 Whether the training/ awareness for field/ground staff involved in conduct and handling of material of CFTs and Good Agricultural Practices is proposed

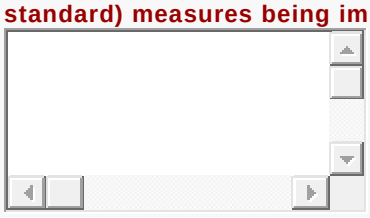
Yes No

- If Yes, provide relevant information
- If No, provide reason(s) there of

L.3 Reproductive Isolation

--Select--

L.3.1 Describe the reproductive isolation (according to the Indian minimum seed certification standard) measures being implemented for this trial and give details



L.3.2 Whether the size of trial site(s) is adequate to maintain isolation distance from experimental plot(s) according to the Indian minimum seed certification standard?

( ) Yes (•) No

- If Yes, provide relevant information
- If No, provide reason(s) thereof

L.4 Transportation

L.4.1 Describe how genetically engineered seed and/or plant material will be packaged for transport

L.4.2 Describe how containers and/or packaging material will be sanitized and/or disposed of after use.

L.4.3 Describe how containers or packets containing genetically engineered seed or plant material will be labelled.

L.4.4 Describe how safe custody will be ensured and the type of records that will be retained.

L.5 Planting

L.5.1 How will material be planted?

( ) By Hand (•) Mechanically

L.5.2 Will any unmodified plants of the same or a related species be planted at the trial site location?

Yes No

L.5.3 If any equipment is to be used during planting, explain how it will be cleaned on the trial site.

YES

NO

L.5.4 Describe how surplus planting material will be rendered nonviable at the trial site.

L.5.5 Describe how quantities of seed planted and any excess will be recorded.

L.6 Pesticide(s)/herbicide(s) Applications

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

L.6.1 Name of the proposed pesticide(s)/ herbicide(s)

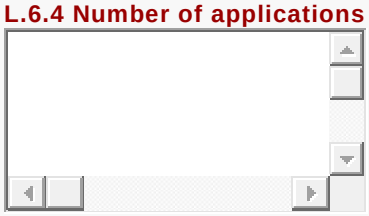
L.6.2 Whether the application to CIB & RC has been made for registration of pesticide(s)?

Yes No

- If Yes, briefly explain the status of the application
- If No, provide reason(s) thereof

L.6.3 Active ingredient(s)

L.6.4 Number of applications per crop season



L.6.5 Anticipated stage(s) of crop at which pesticide(s)/ herbicide(s) will be used

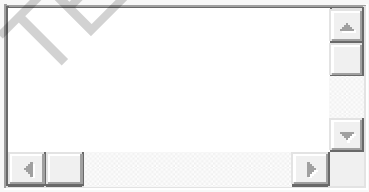
L.6.6 Total area to be sprayed (square meters) along with details of treatment plot(s) to be sprayes

L.6.7 Steps taken to avoid spray drift to nearby plots

L.7 Harvesting

L.7.1 Will plants be allowed to set seed?

○ Yes ◉ No



L.7.2 How will material be harvested?

○ By Hand ◉ Mechanically

L.7.3 Will any harvested plant material be retained from the trial?

Yes No

L.7.4 Describe the storage method and storage location of harvested materials, if applicable.

L.7.5 If any equipment is to be used during trial, explain how it will be cleaned on the trial site.

L.8 Monitoring the trial site

L.8.1 Describe the extent and frequency of trial site monitoring during the current growing season.

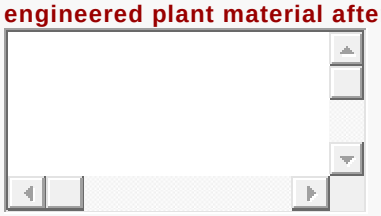
L.8.2 Describe what monitoring results will be recorded.

L.8.3 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.

L.9 Emergency plans for accidental release

L.9.1 Describe your contingency plans in the event of an accidental release of seed or plant material or a breach of reproductive isolation.

L.9.2 Describe your contingency plan in the event of an unexpected spread of genetically engineered plant material after an accidental release.



PART 8

O. Provide appropriate references or any other relevant information from published scientific literature. :

Upload

O.1 Trait based efficacy

O.1.1 Whether data on Efficacy of the trait generated in laboratory/contained conditions ?

If Yes,provide details of the study(Objective, Protocoal and data).

Yes No

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O.1.2 Objective and Protocol proposed to be conducted.

Upload

O.1.3 Data proposed to be generated.

Upload

O.2 Morphological and Phenotypic characters to be studied.

O.2.1 Reproductive and Survival Biology (crop growth, plant height, dry matter yield) in comparison with non-GE comparators

Upload

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O.2.2 Yield performance of GE in comparison with non-GE comparators & checks

Upload

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O.2.3 Whether any earlier generated reports to be furnished ?

If Yes,provide details of the study.

(•) Yes ( ) No

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please upload only .pdf,.doc,.png,.gif and .docx file.

P. Confidential Information :

( ) Yes (•) No

Q. Whether the genetically engineered crops/ plants and product(s) thereof under consideration, have been deliberated earlier by the RCGM? If so, provide relevant 'Unique Application Code (UAC)' assigned for each of those deliberations

	S.No.	Unique Application Code (UAC)
☐	01	

R. Declaration by the applicant:

- I declare that I am familiar with, and agree to comply with all the provisions mentioned in the regulations and Guidelines on Biosafety of recombinant DNA Research and Biocontainment,2017 and Guidelines & Handbook for Institutional Biosafety Committee(IBSC),2011 and other applicable Guidelines, as modified time to time by the Goverment of India.
- I would ensure that all investigators/ researchers and staff working in the area of HMOs, recombinant DNA, GMOs/LMOs and product(s) thereof understand and follow the aforesaid biosafety guidelines.
- I assure that adequate training would be conducted to create awareness about compliance requirements while working with biorisk inherent microorganisms and/ or recombinant organisms.
- The HMOs, GMOs/LMOs and product (s) thereof (transferred material), if any, will be utilized for RCGM approved purpose(s) only.
- I also assure that deviations to the above provisions, if any; arising out of the experiments would be brought to the notice of the Chairman-IBSC and the Member Secretary-RCGM immediately.
- I also undertake that provisions of the Biological Diversity Act,2002 are complied with.
- I am aware that making false or misleading statements may attract penalty under the Environment (Protection) Act, 1986.

Name :

Designation : **Signature with stamp & Date:**

S. Certified & forwarded by the chairman of the IBSC :

Submission of Minutes of the IBSC meeting is obligatory. Kindly note that minutes older than two years are void. Please refer FAQs for submission of minutes of the IBSC meeting

- I certify that the information contained in this form has been checked by the Institutional Biosafety Committee (IBSC) and found to be complete.
- I further certify that investigator(s), researcher(s) and staff intended to work with HMOs, recombinant DNA, GMOs/LMOs and product (s) thereof have adequate training and experience for the proposed dealings.
- I undertake that liability of IP issues, if any, on the product under investigation, such as infringement of intellectual property shall be borne by the organization.
- The proposal set out above has been considered and approved by the IBSC in its meeting held on [ ] as the agenda item no. [ ] and is forwarded to RCGM for further necessary action (Copy of the duly signed minutes of relevant meeting is enclosed).

[ ]

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Please upload only .pdf,.doc,.png,.jpg and .docx file.

Name :

Designation : **Signature with stamp & Date:**

Chairman