



Frequently Asked Questions CONFINED FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS



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New Delhi

2024



1. What are confined field trials?

Confined field trials are small-scale field experiments to address the biosafety requirements and evaluate the performance of specific trait(s) in genetically engineered (GE) plants¹.

Embodied in this definition are three important considerations:

1. Confined field trials are of limited size, typically carried out on a small scale.
2. Confined field trials are experimental activities, conducted to collect data, including data regarding potential biosafety impacts.
3. Confined field trials are conducted under conditions of reproductive and physical isolation known to mitigate the dissemination of the experimental plant, its persistence in the environment, and its introduction into human food or livestock feed.

These are similar to field experiments done for conventional breeding, but they are confined.



2. Why are the field trials of GE plants “Confined”?

Field trials of GE plants are undertaken in confined conditions so as to prevent exposure during trials since these products are still under safety evaluation as per regulatory requirements.

Emphasis is on the implementation of the practices designed to prevent exposure or escape of GE materials outside the trial site.

3. Why are confined field trials undertaken?

Field experiments are an essential step in the development of crop varieties, regardless of whether these varieties are produced by conventional plant breeding or by advanced techniques of modern biotechnology, to determine the performance of new variety in realistic conditions over a range of locations and environments.

In case of GE plants, scientists discover new beneficial traits by identifying genes and carrying out genetic transformations in research labs and greenhouses (contained conditions). However, these results must be validated under field conditions and biosafety and environmental safety of plants containing these traits must be evaluated before new varieties containing these traits can be developed for use by farmers. Therefore for advancing research, confined field trials are conducted in a real-life environment to further evaluate in terms of efficacy, agronomic performance and potential environmental impact.



¹GE plant: A plant in which the basic genetic material i.e. DNA has been altered or modified using genetic engineering techniques to improve the attributes or make it perform new functions. GE plants are also referred as genetically modified (GM) plants, transgenic crops, or biotech crops.

4. What is the difference between contained conditions vs. confined field trials?

Contained conditions refer to working with GE plants within contained facilities such as a laboratory, a greenhouse, a nethouse and areas used for the storage and handling of experimental GE plant material. There is a physical barrier or barriers to avoid direct contact of GE plants with the environment under contained conditions.

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.

Confined field trials represent a greater degree of environmental exposure than work performed in contained facilities, but with confinement to prevent exposure or escape of experimental GE material to environment and/or food chain.

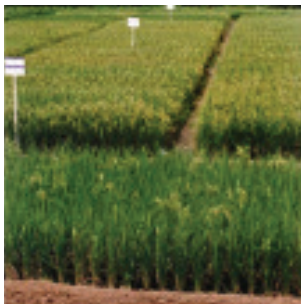
Contained conditions

Laboratory or
Greenhouse experiments



Confined Field Trials

Small-scale isolated
Experimental field trials



Unconfined Use

Farmers Fields



5. Can GE plants be scientifically evaluated in the greenhouse only?

No, data which fully represent the response of plants to the conditions likely to be encountered in a particular agro-ecological environment can be collected only by growing the plants outdoors in confined field trials as it is virtually not possible to comprehensively replicate the outdoor environment in a greenhouse.

Greenhouse studies are useful only in initial stages as these are conducted in controlled environment and are inadequate to predict how a plant will perform when grown outdoors under natural environmental conditions. Also greenhouse studies cannot be performed at a scale sufficient to comply with these regulatory requirements.

Without the field data, developers cannot make scientifically tenable predictions about the performance of the plants in the field or about the environmental safety of the plants



6. What are the types of confined field trials in India?

The types of confined field trials generally undertaken during the development of GE plants in India include:

- i. **Event Selection Trials** : Planting small plots comprised of several to dozens of events of the same plant species for a preliminary evaluation to facilitate the selection of one to a few events² for further evaluation.
- ii. **Biosafety Research Level - I (BRL-I) Trials** : 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, per Applicant, per crop season.
- iii. **Biosafety Research Level - II (BRL-II) Trials** : 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, per Applicant, per crop season.
- iv. **Experimental Seed Production** : Production of seeds or planting material for the selected events under confined field trial conditions for the next phase of trials.
- v. **Production of plant material for food and feed safety studies** : To generate plant material under confined field conditions for undertaking various food and feed safety studies such as toxicity and feeding studies.
- vi. **Other environmental safety studies** : Trait or crop specific studies under confined field conditions for generating data on environmental safety e.g., residue analysis, crossability studies etc.



7. How is confinement ensured during conduct of confined field trials (Guiding Principles)?

Field trials can be confined by maintaining reproductive and physical isolation known to mitigate the dissemination of the experimental plant, its persistence in the environment, and its introduction into human food or livestock feed.

Confinement of field trials is accomplished through appropriate management measures for:

- i. **Material Confinement**- To prevent eating by humans or livestock by maintaining control of GE plant material at all times.
- ii. **Genetic Confinement**- To prevent any pollen mediated gene flow from the trial sites by ensuring reproductive isolation methods such as maintaining isolation distance, bagging etc.
- iii. **Post-Harvest Land Use Restrictions**- To prevent persistence by ensuring that the GE material and any volunteer arising from the trial site are completely destroyed.



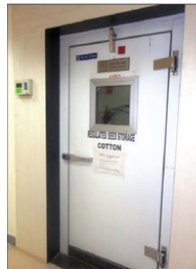
² **Event** : A genotype produced from the transformation of a single plant species using a specific genetic construct.

8. What are the measures undertaken to ensure material confinement?

Material confinement is the most critical control point in the proper management of confined field trials and requires implementation of effective and documented control processes.

Measures undertaken to ensure material confinement include

- Appropriate packaging and labeling of GE plant material to and from the trial site
- Secured storage
- Cleaning of all equipment used for various activities at trial site
- Disposition of all the plant material generated during the trial
- Security of the trial site



9. What are the measures undertaken to ensure genetic confinement?

Different methods are used in the conduct of confined field trials to achieve genetic confinement, also referred to as reproductive isolation. The goal is to ensure that regulated GE plants do not pollinate sexually compatible plants, including cultivated plants or free-living plants of same crop species, or any wild plants of a species sexually compatible with the plant.

Commonly used reproductive isolation methods are

- Spatial isolation by maintaining a minimum isolation distance
- Bagging reproductive plant parts
- Temporal isolation by staggering the planting
- Removal of floral structures
- Pollen trap rows
- Early termination prior to anthesis and pollen shed
- Artificial barriers

Effective methods of reproductive isolation are determined on case-by-case basis based on reproductive biology of the plant species. Measures are crop specific. Not all trials use every method.



10. What is the basis of isolation distance prescribed for a confined field trial?

Maintaining a minimum isolation distance is the most commonly used method to restrict the pollen-mediated gene flow. These distances vary for different crops and may also be used in conjunction with other methods on a case-by-case basis.

Isolation distances prescribed by the regulatory authorities are based on accepted distance for pure seed production, which have been prescribed under the Indian Minimal Seed Certification Standards by Department of Agriculture and Cooperation, Ministry of Agriculture.

These standards are developed based on years of experimental data and have been accepted globally as standard methods for reproductive isolation by regulatory authorities.

Minimum isolation distances for crops prescribed in India under field trials

Crop	Minimum isolation distance
Cotton	50 m
Maize	200 m
Rice	10 m
Brinjal	200 m
Okra	250 m

Source: http://agricoop.nic.in/imagedefault/seed/INDIAN_MINIMUM_SEED_CERTIFICATION_STANDARDS.pdf

11. What are the measures undertaken for Post-Harvest Land Use Restrictions?

Confined field trials are conducted in such a manner that the regulated GE plant, or its progeny, does not persist in the environment. A period of post-harvest restriction and monitoring is prescribed by the regulatory authorities depending on the plant species and particularly its dormancy characteristics. The measures include:

- Monitoring of area under restriction during post-harvest period.
- Destroying prohibited plants (volunteers or sexually compatible species) prior to flowering
- Not planting of same or sexually compatible species in the restricted area during restriction period.



12. What are crop specific biology documents?

Crop specific biology documents are useful reference for conducting confined field trials and safety assessment. Biology documents provide an overview of pertinent biological information on the untransformed (i.e., conventional or non-transgenic) species as a comparator against which GE plants are evaluated during the safety assessment process. These documents define the baseline information which serves as a resource tool for planning of confined field trials by the developers, researchers and the regulatory agencies.

Ministry of Environment, Forest & Climate Change (MoEFCC) and Department of Biotechnology (DBT) prepared several biology documents for crops viz. Cotton, Okra, Rice, Maize, Sorghum, Mustard, Potato, Papaya, Chickpea, Pigeonpea, Tomato, Rubber and Brinjal. Developers of GE crops are required to submit biology documents specific for their crops to be tested, prior to initiating a confined field trial.



13. How are trial sites selected?

The suitability of the trial sites proposed by applicants takes into consideration the location, crop specific requirements for optimum growth and expression of trait, presence of sexually compatible species and proximity to protected areas etc.

Confined field trials are usually carried out at experimental stations such as those under the control of National Agricultural Research Systems (NARS), local universities, or private sector research units. In case where they have to be conducted in a farmer's field, the land has to be leased for sufficient duration of time including the post-harvest restriction period.

The organizations conducting field trials have to be staffed by competent scientists with sound experience in the safe conduct of field trials and have capacity to evaluate the performance of new varieties for farmers.



14. Who regulates conduct of the confined field trials of GE Plants in India?

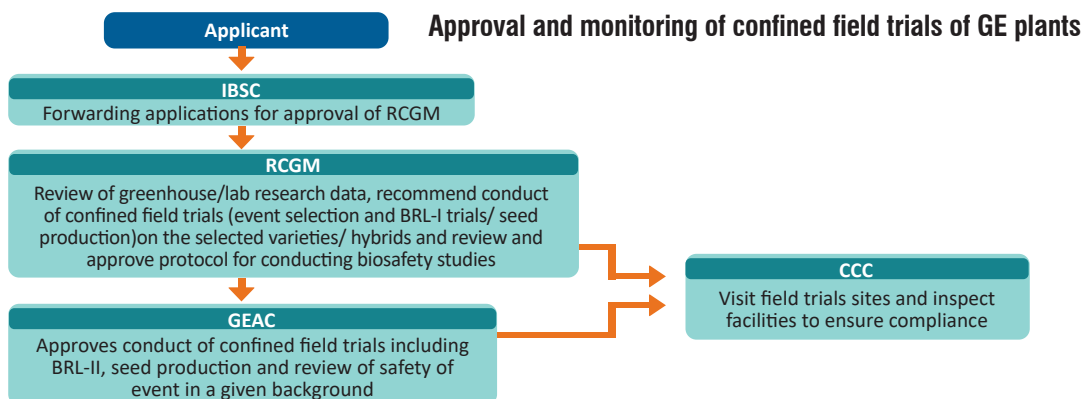
Confined field trials of GE plants are regulated in India as per the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989 (Rules, 1989) notified under the Environment (Protection) Act, 1986. These rules are implemented by the MoEFCC, DBT, Ministry of Science and Technology and State Governments through various committees.

Six competent authorities, notified under the Rules, 1989 include Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM), Genetic Engineering Appraisal Committee (GEAC), State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC). Out of these, IBSC, RCGM and GEAC are involved in review and approval of confined field trials. SBCC and DLC are responsible for monitoring.

The Government of India follows a policy of case-by-case approval of confined field trials of GE plants. The regulatory steps are as follows:

- Initial assessment of an application at the institutional level itself.
- Review by IBSC based on information generated in lab/greenhouse.
- Review by RCGM and recommended to GEAC.
- Final approval of all confined field trials by GEAC.

There is a requirement of seeking No Objection Certificate (NOC) from the state government for each location of confined field trial by the applicant except event selection trials to be conducted in the institutional premises.



15. Who monitors/inspects confined field trials? What is the role of State Government agencies?

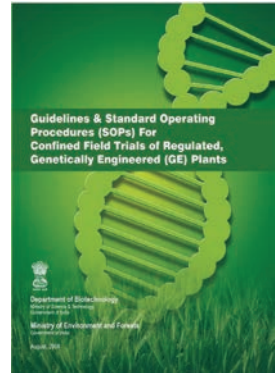
Each field trial is monitored by a Central Compliance Committee (CCC) constituted for a specific authorization on a case-by-case basis by RCGM and GEAC. The CCCs can inspect confined field trials at the time of planting, during the growing and harvesting season and during the period of post-harvest land use restrictions. They also have the authority to inspect contained facilities that may be used for the storage of regulated GE plant material.

Representatives from state agriculture department and state agricultural universities are members of CCC, in addition to subject-specific experts and nominated member of RCGM/ GEAC. Designated State Government agencies are also provided with relevant details viz. map of trial site, trial design, planting information and harvest information.

16. Do we have guidelines and SOPs for confined field trials of regulated GE plants in India?

Yes, Guidelines and Standard Operating Procedures (SOPs) for the conduct of confined field trials of regulated, GE plants in India have been prescribed by the regulatory agencies under Rules, 1989. These include:

- Guidelines for the Conduct of Confined Field Trials of Regulated, GE Plants
- Application Form for Confined Field Trials
- Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, GE Plants for: transport of regulated GE plant material, storage of regulated GE plant material, management of confined field trials, harvest or termination of confined field trials and post-harvest management of confined field trials
- Recording Formats for Transport and Transport Inventory List, Storage, Storage Inspection and Inventory, Planting, Spatial Isolation, Harvest/Termination, Post-Harvest Monitoring, and Corrective Action
- Guidelines for the Monitoring of Confined Field Trials of Regulated, GE Plants
- Comprehensive Glossary of Terms



The guidelines can be accessed at <https://geacindia.gov.in/guidelines-and-protocols.aspx> and https://ibkp.dbtindia.gov.in/Content/Rules_. Application forms are also required to be submitted online at the above portals

17. What are terms and conditions specified for conduct of confined field trials?

Confined field trials are performed under stringent terms and conditions to confine the experimental material. Specific conditions to be laid for each confined field trial vary according to the crop, the introduced trait and the locations/environment.

These terms and conditions also serve as a guide for the CCCs deputed by RCGM and GEAC for inspecting the field trial site.

Standard terms and conditions applicable to all confined field trials are as follows:

- All confined field trials of GE plants are to be conducted in accordance with the “Guidelines and Standard Operating Procedures for CFTs of regulated, GE plants, 2008”.
- No seed or other plant materials from the confined field trial may enter the human food or animal feed chains.
- A Trial-in-Charge is to be designated for each trial site, who would be responsible for conduct of the trial
- All the plant material that is not retained for research purpose is destroyed by supervised incineration after completion of the trial.
- A notice board indicating the purpose and duration of the confined field trial along with other key details is to be mounted at the trial site.
- Adequate records of all activities including trial site compliance, transportation, storage, management, harvest/disposition and post-harvest monitoring are to be maintained by Permitted Parties.
- In the event of any accidental or unauthorized escape of GE plant material, the regulatory authorities are to be immediately informed, positively within 24 hours.

In addition, the applicants are required to submit a validated protocol for detection of a GM crop to regulatory authorities.



18. What are the safety assessment requirements prior to conduct of confined field trials?

Risks from confined field trials and risks from unconfined releases are assessed and managed differently.

For an unconfined (commercial) release, there is little or no possibility of controlling the exposure component of risk because the intention is to introduce the GE plant widely into commercial agriculture. Rigorous risk assessment is required and regulators must be satisfied that potential hazards are not significant, to minimize risk both to the environment and to people and animals.

Conversely, for a confined field trial, where the potential hazards may not be fully understood without data collected during the trial, the focus is on minimizing environmental exposure.

It is a common misunderstanding that confined field trials should be subject to essentially the same risk assessment process as for commercial releases.

A detailed risk assessment is more correctly applied to the environmental release of GE plants for unconfined or commercial cultivation and not for field trials as the very purpose of conduct of field trials is to test efficacy and safety of a GE plant in real life environment.

GE plant development cannot advance past the laboratory stage unless the confined field evaluation of GE plants is permitted by regulatory authorities.

19. Can the confined field trials be conducted safely?

Yes, the safe conduct of confined field trials can be accomplished through the combination of science-based risk mitigation measures and trained field personnel dedicated to abiding by the terms and conditions of trial approval and by timely monitoring.

Since the first trials of a GE crop were carried out in Canada and the US in 1987, lakhs of confined field trials have been conducted safely in various countries around the world.

In India, confined field trials of more than 20 crops with multiple traits have been conducted by public and private sector organizations.

An indicative list of GE plants on which confined field trials have been conducted in India

Plant	Trait	Plant	Trait
Banana	Vitamin A and iron enhancement	Pigeonpea	Insect resistance
Brinjal	Insect resistance	Potato	Tuber sweetening, fungal resistance
Castor	Insect resistance	Rice	Insect resistance, disease resistance, hybrid seed production, nutritional enhancement
Chickpea	Abiotic stress tolerance, insect resistance	Rubber	Abiotic stress tolerance
Corn	Insect resistance, herbicide tolerance	Sorghum	Insect resistance, abiotic stress tolerance
Cotton	Insect resistance, herbicide tolerance, virus resistance	Sugarcane	Insect resistance
Groundnut	Virus resistance, abiotic stress tolerance	Tomato	Insect resistance, virus resistance
Mustard	Hybrid seed production, abiotic tolerance, product quality improvement	Watermelon	Virus resistance
Okra	Insect resistance, virus resistance		



20. What are the benefits of confined field trials?

Confined field trials serve multiple purposes.

For the farmers, confined field trials are essential for development of new technologies that provide solutions to their problems and eventually increase their incomes.

For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel plant/trait combinations in an open environment. For the technology developers, confined field trials are necessary to collect the agronomic and ecological data required to complete environmental safety assessment of a GE plant. In addition, confined field trials provide plant tissues for other regulatory studies such as the levels of protein expression from any newly introduced genes, in a variety of plant tissues, over the course of plant development. Confined field trials also permit the production of sufficient quantities of plant material to conduct nutrient compositional analyses and, when necessary, for use in livestock feeding trials.

From a policy standpoint, the implementation, monitoring, and enforcement of effective risk management strategies for confined field trials helps biosafety regulatory authorities in ensuring compliance to stipulated regulations.

To summarize conduct of confined field trials facilitates development of new GE plants, adapted to local needs and benefit to farmers.



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