



RESEARCH ARTICLE

Confined field trials and regulation of genetically engineered plants

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Received: 30 October 2025; Accepted: 20 March 2026; Available online: Version 1.0: 08 July 2026

Cite this article: Aarti S, Shamim M, Manish K, Aradhana S, Ayon A, Mahesh K. Confined field trials and regulation of genetically engineered plants. *Plant Science Today*. 2026; 13(sp5): 1-11. <https://doi.org/10.14719/pst.12491>

Abstract

Varietal trial of a non-transgenic experimental material generated from modern or traditional plant breeding methods can be tested in any region that suits the respective crop without any confinement. However, a transgenic experimental material developed following genetic engineering (GE) requires its testing in confinement to assess its safety as human food/commercial use/animal feed or to determine its impact on ecology and environment. Given the gravity of impact, a genetically engineered crops are developed following, several guidelines, rules, Acts, framed by the countries involved in transgenic research. One such guideline in the Indian context is “Guidelines for Research in Transgenic Crops, 1998” and international guidelines in India are abstracted from Organization of Economic Cooperation and Development (OECD) and Cartagena protocol. These guidelines set out rules and procedures to regulate genetically engineered (GE) crop field trials. In India there are regulatory bodies from the ministry level to local level (districts and research institution) that execute, monitor and authorise the use of GE plants or animals. The GE crop/are raised in “confined field trials” (CFT) with the objectives to collect data on its potential threat to environment, impact as feed and food of livestock and human respectively. In India CFTs are conducted on a case-by-case basis; no generalised protocols are applied to all types of GE crops under trial. While the regulation of GE crops is “process” based and “product” based in European Union (EU) and USA respectively.

Keywords: confined field trials; genetic engineering; genetically modified organism; guidelines for research in transgenic crops, 1998

Introduction

Genetically modified organisms (GMO) are a debatable topic on safety issues because still scientific community seems divided and puzzled and unfortunately not developed a consensus on its safety (1–3). Around world, GMOs are invariably clung to one or other controversies (4). In India too, its fate is no different, genetically engineered crops viz., *Bacillus thuringiensis* (Bt) brinjal has been forced to moratorium (5, 6); and Dhara mustard hybrid-11 (DMH-11) has been subjected to ex-ante impact assessment (7). In 2001, ICAR, New Delhi, India, Director General Dr. Panjab Singh halted the commercial release GM mustard on ground of insufficient data (8). Two major insights from aforementioned incidents of Bt brinjal and DMH- 11 for government, scientists and end consumers can be : firstly, to build solid acceptance among common people about GMO and secondly, to strengthen the GMO related trials in systematic and scientific way so that end products can be accepted by the consumers and scientific community that unfortunately remains divided on safe use of GMOs. Hence, in most of the countries undertaking development or cultivation of GMO has a regulatory system and bodies to supervise the experiment/research/study on genetically engineered organisms (plants or animals) viz., EPA, FDA and USDA in USA and European Commission in European Union (EU) (9). Likewise, India too has an extensive regulatory framework for research, trials and introduction into market of any GE crop/plant (10).

In agriculture, plant breeding techniques are used to develop varieties with improved yield or quality. The techniques used are both modern, viz., marker assisted plant breeding and traditional methods, viz., selection and hybridisation based (11–13). Transgenic crop breeding provides a new realm in field of plant breeding to generate varieties with novel traits and improve crop in an unprecedented way (14–16). Flavr Savr, the first GMO crop variety, was introduced nearly three decades ago and changed the whole marketing system of tomato by increasing the shelf life of tomatoes (17). Since then, transgenic crops with novel traits have been introduced in number of crops. In India only currently many transgenic crops viz., cotton, rice, wheat, maize, brinjal, potato, sorghum, mustard, groundnut, cauliflower, okra, chickpea, pigeon pea, castor, sugarcane etc. have been studied (18). However, the ill effects of transgenic crop cannot be completely overlooked also; one such example is GM soy which has alerted amino acids proportions in comparison to non-GMO soy crop. And these modified proportions of amino acid proved to trigger allergic reactions in people allergic to Brazilian walnut (19). Naturally, soya crop lacks methionine, consequently, GM soya crop was developed by introducing methionine rich 2S albumin gene from Brazilian nut into soyabean to supplement this deficiency. Since the Brazilian nut is known to give allergic reactions, scholars studied allergenicity of GM soya. They ran tests: radioallergosorbent tests and sodium dodecyl sulfate-polyacrylamide-gel electrophoresis (SDS-PAGE) tests were

performed on four and nine subjects respectively. In their study they concluded that the subjects who were allergic to Brazilian nut showed allergic reactions to transgenic soya too (19). There are literatures to substantiate the very fact that GE crops affect hematology, serum biochemistry, histopathology or gastrointestinal microbiota in animals when used as animal feed (20–22). The cultivation of GMOs is almost negligible in EU with an exception to Spain which takes up substantial production of GMOs (23). In India in 2012, Lok Sabha released a report on GMO, namely: “Cultivation of Genetically Modified Food Crops – Prospects and Effects”. In this report government showed concern over use of GE crops as food, feed and its repercussion on environment (20).

The debate on GMO being good or bad will keep on because its neither bad nor absolutely good; the grey line between this absolute white (good) and absolute black (bad) is quite wide and so is the possibility of a GMO becoming a savior (24, 25). Moreover, area under GE plant cultivation is increasing (26, 27). Transgenic technology can complement traditional and modern methods and play a significant role in crop improvement (28–30). Consequently, it becomes obligation to conduct safety assessments on new genetically engineered products to obtain sufficient scientific data which can assist in substantiating safe use of GMO and overcome consumer reluctance in accepting GMO products.

In agriculture, when a new variety is developed it undergoes a rigorous trial to generate data of its suitability and superiority, novelty in comparison to others to be identified, notified and further certified as a variety in future (31). Moreover, such trials can be conducted at any research station in India or in foreign land if required without prior permission on biosafety issues from any organisation which regulates GE crop trials in India (6). Nevertheless, for genetically engineered plants (GEp) the whole premise of ethics, rules and regulations changes; and field trials of GEp are conducted with proper permission of regulatory bodies in confinement or containment only. Accordingly, there are contained trial and confined field trial (CFT) are practices for GE crops (32). Different ministries, departments/institutions, committees at national, district and local level function in cohesion following a set of comprehensive guidelines derived from rules and acts for the safe and proper execution of CFT (33). This manuscript, delineate the nature, objective of CFT and regulatory framework of genetically engineered plant (GEp) in India, EU and USA.

Objective of confined field trials

Genetically engineered plant has novel traits and unpredictable phenotypes wherefore requires stringent safety evaluations to intercept any accidental release or escape of GEp into the human or animal food or feed and to environment without prior permission of release (33–35). These safety evaluations are conducted in CFT. Genetically engineered plant in this manuscript refers to any plant/genotype which has been genetically modified using modern transgenic technology and required to be tested before release into environment or prior to human or animal use. By 2018 a total of 21 different crops had been permitted to conduct CFT in India (36). After the success of Bt cotton in India many new transgenic events were developed in crops viz., brinjal, cabbage, cauliflower, tomato, lady's finger, rice, corn and groundnut and tested in CFT (36). The rise of study on GMO (including GEp) in India can be testified with establishment of 652 Institutional Biosafety

Committee (IBSC^s) and documented hundreds of meeting meetings Genetic Engineering Appraisal Committee (GEAC). Confined field trial plays a pivotal role in GEp trials that can be acknowledged by examining the key activities conducted in CFT; outlined below.

Primarily, CFTs are conducted to study effect of genetic modification, risk of GEp as food feed and its impact of environment.

1. Effect of genetic modification and protein characterisation: This factor focuses on evaluation of impact of GEp morphological and biochemical traits on ecology. It is performed by:

- i. Characterisation of GE material (crop) is studied viz., all phenotypic expression
- ii. Characterisation of non-modified crops from which GEp had been generated
- iii. Characterisation of donor organism
- iv. Assessing inheritance and stable performance of construct (inserted gene) in the GE material
- v. Molecular characterisation of GE trait
- vi. Monitoring function/specificity/mode of action of inserted gene
- vii. Quantify protein level
- viii. Search history of safe use and consumption

***The list of Institutional Biosafety Committee (IBSC) can be substantiated from the link address:**

[https://ibkp.dbtindia.gov.in/PageContent/ShowBrowsedFile?FileName=20240913162505947_List%20of%20Institutional%20Biosafety%20Committee%20\(IBSC\).pdf&FPath=E:%5C%5CDBT_Content_Test%5CCMS%5CCommittees/20240913162505947_List%20of%20Institutional%20Biosafety%20Committee%20\(IBSC\).pdf](https://ibkp.dbtindia.gov.in/PageContent/ShowBrowsedFile?FileName=20240913162505947_List%20of%20Institutional%20Biosafety%20Committee%20(IBSC).pdf&FPath=E:%5C%5CDBT_Content_Test%5CCMS%5CCommittees/20240913162505947_List%20of%20Institutional%20Biosafety%20Committee%20(IBSC).pdf)

Food and feed safety: In this factor comprehensive nutritional analysis is performed to understand the biosafety of GEp as food and feed. It can be done in following ways:

- i. Assessment of toxicity caused to animals if used as animal feed (acute and sub-chronic studies)
- ii. Testing allergenicity, heat stability and susceptibility of the construct protein expression
- iii. Analysis of composition of the GEp in respect to non-modified plants on parameters viz., nutrients, anti-nutrients, secondary metabolites and physiologically active substance.
- iv. Examining effect of processing

Environmental safety: Likelihood of GEp becoming weed is studied in this factor by:

- i. Quantification of protein of introduced trait
- ii. Collection of data from CFT
- iii. Phenotypic characterisation of GEp
- iv. Study of weediness nature of GEp
- v. Observing unpredictable changes in GEp during the plant growth stages
- vi. Susceptibility of GEp to disease and pests
- vii. Calculating impact on ecology and environment (soil micro flora)
- viii. Examining gene flow pattern

Level of confinement of genetically engineered plants in a confined field trial

Confinement in a CFT is achieved by complying with guidelines, SOPs, monitoring manuals etc. outlined by the regulatory authorities concerned during the entire growth stages of a crop (harvest, post-harvest and even few years after post-harvest). Basically, three types of confinement are practiced in a CFT (37): a) material confinement is done by restricting accidental contamination of feed or food by GEp. This is accomplished by i) properly labelling of GEp material during storage, transport, disposing or packaging; ii) cleaning all farm equipment/tools/vehicles used in field either for agronomic practices, storage and transport; iii) termination of biological yield after harvesting by incinerating or other measures which ensures complete destruction; iv) restricting unwanted movement of animals or humans into the CFT area. b) genetic confinement is also important to avoid contamination of non-GMO crops with GMO crops of same species which can occur in case of uncontrolled pollen dissemination. The pollen grain movement can be kept under check by practicing isolation (spatial, temporal), bagging of reproductive flower parts, creating barriers (artificial or by planting rows of plant which can trap pollen of GEp). c) post-harvest restriction to use trial areas for plantation: This is achieved by prohibiting non-GMO crop production in CFT area in the following year/season. Crops of same crop species as of the event crop species is strictly prohibited to avoid any cross-contamination via volunteer plants for one or more years/seasons.

Types of confined field trial

The experimental trials of GEp can be conducted for several purposes; accordingly, CFTs can be broadly classified into two types (37).

Based on objective of research

- Event selection trials:** It is a preliminary evaluation in which multiple events of a crop species are planted to further select those events that require trials.
- Biosafety research level 1 trials:** Such types of CFT are regulated by Review Committee on Genetic Manipulation (RCGM). In which trial size can be 1 acre/trial/site/location/location/plant species/construct combination/applicant/crop season **. Total number of such trials can be maximum 20 in number.
- Biosafety research level 2 trials:** Such type of CFT are regulated

by GEAC. In such trials, size of trial area can be 2.5 acre/trial/site/location/plant species/construct combination/applicant/crop season **. Total number of such trials can be maximum 8 in number.

- Experimental seed production trials:** Such trials are meant for carrying out seed production of selected events for the next phase of trials.
- Trials for food and feed safety assessment:** Trials are conducted to produce biological yield which is further used in lab to study suitability of GEp as food feed, examine presence of any toxin etc.
- Trials for specific environmental safety studies:** Trials are conducted to obtain data to study impact of GEp on environment and ecology.

(**can be changed based on rationale of research)

Based on containment of GEp trials

Contained field trials and CFTs are the two types of trials conducted for GEp in agriculture. These two types of trials differ from each other in area, scale, containment required etc. A comparative study of contained trial and CFTs of GEp and field trial of non-GE crops is given below (Table 1).

Overview of applications used in GEp/GMO research and development

Cultivation of GEp, requires proper authorisation from GEAC (6, 38). Whereas, for non-GEp no such authorisation from any govt agency is required. Once the authorisation is granted, a person can take up commercial production of GEp, however the cultivation must be done in isolation. Some of the measures taken to ensure isolation or prevent any accidental contamination of non-GEp field from GEp field can be done by maintaining physical barrier (pollen trap), isolation distance, inducing flowering asynchrony or crop rotation (39–41). Research trials of GEp are conducted by taking proper authorisation from the concern authorities and trials are conducted either in lab following BRL or in field called confined field trials.

In field of GE any product whether of plant/animal/microorganism requires testing; thorough tests or trials are conducted to assess the safety of GMO, calibrate potential risks and formulate measures to alleviate those risks. Now to conduct those tests and trials, respective applications need to be

Table 1. Contained field trials Vs confined field trials (37)

Non-GMO field trials	Contained trials (CT)	Confined field trials (CFT)
Conducted in open field. Area of field can vary depending on crop.	CT conducted mostly in laboratories or greenhouse	CFT are isolated experimental field trials conducted in field (area can vary but maximum area is limited to 1–2 ha ^a)
There is contact between crops of non-GMO field trials and environment	In contained trials there is no contact between GE organisms or material with outer environment	In confined field trials there is restricted contact between GE organisms or material with environment
Isolation distance or physical barrier is not required. (exception: sick plot)	There is physical barrier between experimental area and environment	There is physical barrier between experimental field and environment
Guidelines that regulate non-GMO are derived from:	Guidelines which regulate CT are- Research in Transgenic Plants, 1998	Guidelines that regulate CFT is-
Seed Act (1966)	OECD	“Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells” notified under Environment (Protection) Act, 1986, commonly referred as Rules, 1989.
Trial is conducted to collect data on performance of new experimental material generated by the plant breeder	Objective of trial is to collect safety and regulatory data	Objective of trial is to collect safety and regulatory data

Maximum area can be changed based on rationality of the experiment; GMO: genetically modifies organism; OECD: Organization of Economic Cooperation and Development; GE: genetically engineered.

submitted that are available at government official sites in India: <http://dbtbiosafety.nic.in>. The applications are submitted to IBSC, for import/export/for research/CFT/release of GM plants/products etc. Name of such applications and their purpose of submission is listed in Table 2.

An event needs to be tested on regulatory guidelines for its safety to human animals and environment prior to its release. The scientist who developed it, can file an application to conduct trials on GEp taking IBSC in confidence. A CFT application is very extensive document and designed to collect information about researchers, research, genetic modified organisms, applicants etc. CFT application has 8 sections (parts) and all parts required to be duly filled in to obtain CFT permit (Table 3).

After getting recommendation from IBSC, applicants can send their application for BRL I and BRL II type of trials to RCGM and GEAC respectively. Few considerable information to be known to the applicant before applying for any CFT are (43):

- Application (new or renewal) should be sent 60 days in advance to RCGM/GEAC after recommendation from IBSC.
- In case of renewal, the past CFT permit and data is also considered
- RCGM/GEAC reviews the application
- Letter of Authorization (LoA) is issued when the application is recommended by the regulatory agencies LoA gives the permitted party a permit number and authorisation of 1 year[®]
- Import permit is required to be obtained by the applicant to RCGM in case regulated plant material must be imported
- If the applicant is not Indian, then he must appoint a person

on his/her behalf; called as Authorised signatory (AS). AS must be permanent citizen of India.

- Number of applications or parts of application to be submitted for getting LoA for an event depends on plant species, phenotypic expression of the event to be tested (Table 4).

On special conditions the authorisation time of 1 year can be extended.

If same phenotype must be tested in CFT: In case of a trial assessing more than one event the applicant is required to submit one application only, but separate part F is required to be submitted. Similarly, for an event if more than one trial is required then, the applicant will submit one application only but two separate parts viz., G and H should be submitted.

If different phenotypes must be tested in a CFT: The applicant is required to submit more than one application depending on number of phenotypes to be tested.

Key elements of confined field trial

In comparison to normal varietal trial or seed production, CFTs are both fundamentally and technically different in context of safety measures, objective and operations followed at all stages of field trial. A successful execution of CFT depends on (33, 35):

1. Meticulous implementation of all guidelines
2. Rigorous monitoring of CFT
3. Stringent practice of SOPs at all stages of trial
4. Precise documentation of all recording formats
5. Assessment of aptness of GEp as food & feed and environment

Table 2. List of different types of application forms required to be filled during GEp/GMO research and development (42)

Objective	Name of the application
Application related to IBSC	
Establishment in the institution/registration	Form A1
Renewal of registration	Form A2
Submission of annual report to RCGM	Form A3
Submission of medical inspection report	Form A4
Classified agreement of IBSC & DBT nominee	Form A5
Applications related to import/export/transfer of GMO or its product	
Importing for research, as food and processed food	Form B1, Form III & Form IV
Exporting for research and development	Form B3
Receiving and transferring within India	Form B5 & Form B7
To conduct research or collect data to assess safety of GMO or its product	
Related to agriculture and environmental research	Form D1
Related to agriculture and environmental biosafety protocols/safety assessment	Form D3
Submission of safety studies of agricultural and environmental research	Form D5
Application for conducting agricultural trials	
GEp field trials	Confined field trial (CFT)
Application for release of GEp/GMO or its product	
Environmental release of GEp or GMO or product of GMO	Form IIB

IBSC: Institutional Biosafety Committee; RCGM: Review Committee on Genetic Manipulation; DBT: Department of Biotechnology; GMO: genetically modified organism; GEp: genetically engineered plants.

Table 3. A brief introduction on parts and information required in a confined field trial application (43)

Parts of a confined field trial (CFT) application	Kind of information sought in the application
Part A	Application type: new or renewal
Part B	Applicant
Part C	Authorised signatory (AS)
Part D	Correspondence address
Part E	Unmodified plant species of CFT
Part F	Modified plant part
Part G	Trial site
Part H	Trial protocol

Table 4. Different Ministries of India and their role in regulation of genetically modified organism in the country (44)

Ministry of India	GMO related function	Rules/Acts to regulate & monitor GMO
MoEF&CC (Ministry of Environment, Forest and Climate Change)	Prioritise human, animal and environmental safety before release of Living Modified Organisms (LMOs)	Rules for manufacture, use, import, export and storage of hazardous microorganisms (HMO)/Genetically Engineered Organisms or Cells, 1989 under the EPA (1986) known as 'Rules 1989'
	Promote biotechnological studies, R&D in industries and universities	The Biological Diversity Act, 2002
DBT (Department of Biotechnology)	Contained use of GEp	Recombinant DNA Safety Guidelines, 1990 Recombinant DNA Safety Guidelines & Regulations, 1994 Revised Guidelines for Research in Transgenic Plants, 1998
	Frame biosafety guidelines for biotechnological research	
MoA (Ministry of Agriculture)	Developing and implementing policies for agricultural growth	Plant Quarantine Order, 2004 by NBPGR
		Seed Policy, 2002 Food Standards and Safety Act, 2006
MoHFW (Ministry of Health and Family Affair)	Making policies aimed at protection and monitoring human health	Drugs and Cosmetics Amendment Act, 1972
MoIC (Ministry of Commerce and Industry)	Export/import related policies	Directorate General of Foreign Trade Notification Relating to Inclusion of GM Policy in Foreign Trade Policy Guidelines for conduct of confined field trials of regulated GE plants, 2008
MoEFCC and DBT	Confined field trials Environmental safety assessment	Standard Operating Procedures (SOPs) for CFTs of Regulated, GE Plants, 2008 Guidelines for monitoring of confined field trials of regulated GE plants, 2008 Guidelines for Environmental Risk Assessment (ERA) of GE Plants, 2016 Risk Analysis Framework, 2016 ERA of GE Plants: A guide for stakeholders, 2016
DBT and ICMR (Indian Council of Medical Research)	Food safety assessment	Guidelines for the safety assessment of foods derived from GE plants, 2008 (Updated in 2012) Protocols for food and feed safety assessment of GE crops, 2008

Guidelines for confined field trial

The guidelines for the safe and effective conduct of CFT are derived from rules, policies and acts passed by the govt of India. The table below enlist the Indian ministries and their role in GMO regulation in India (44).

Monitoring of confined field trial

Trained officials of monitoring team closely observe compliance with CFT rules and regulations by the permitted party. Firstly, a Central Compliance Committee (CCC) is formed by GEAC and RCGM (33, 35). A monitoring team is constituted and an Office of Memorandum is framed in which CCC member names and terms of reference (ethical conduct, fair presentation, independence and evidence-based approach) are mentioned. A copy of the memorandum is sent to the permitted party also called trial-in-charge or facility-in-charge. The function of CCC is to:

- Ensure proper practices of risk management measures during all stages of CFT.
- Document precise lapses found in risk management measures and provide regulatory bodies sufficient evidence of such negligence events.

However, the monitoring team is always advised to avoid interfering in the CFT matters on following grounds.

- Validating any CFT activity in absence of regulatory team
- Giving legal advice to trial-in-charge
- Sharing advice on protocols of research/experiment unless the protocol directly violates risk management measures
- Questioning on objective, research methodology, traits, crop variety or modified DNA sequence

Once an application is recommended by IBSC, the GEAC/RCGM (regulatory authority) or the permitted party themselves requests the monitoring team to start the procedure of monitoring. Inspection of trial field is done by leader of monitoring team himself or by an authorised person appointed by monitoring team leader. The monitoring team visits the CFT at critical stages of crop growth (pre-sowing, sowing, pollination, post-harvest, termination and post termination stages) to inspect trial field; document the inspections; examine storage facility of harvested material of GEp; and prepare concluding report (33, 35). Following complete inspection, the monitoring team a) sends copies of findings to monitor body (MEC, SBCC, DLC); b) presents the findings and conclusion to the permitted party; c) suggest corrective actions (35).

Standard operating procedures (SOP) of genetically engineered plants in confined field trial (45)

Permitted party holds the responsibility to comply with SOPs on following aspects in a CFT during transport of GEp material, storage of GEp, management of CFT, harvest and termination of trials and post-harvest management, documentation of actions taken during CFT (information related to transportation of GEp, inspection of storage facility and inventory, harvest, termination of GEp, post-harvest monitoring, isolation distance, corrective actions, if taken) is a regular practice. In case of accidental release of GEp all the precautionary and preventive measures taken are also documented.

Confined field trial is regularly monitored and inspected by inspecting body for a CFT is called CCC. The CCC constitutes of: Expert scientist (Chairman); Scientists from concerned SAUs; Official personnels from State Agriculture Department; RCGM nominee; and GEAC nominee.

Recording formats of confined field trial (35)

Data are recorded in CFTs in recording formats available for SOPs at the Indian Biosafety Knowledge Portal (dbtindia.gov.in/Content/ApplicationFormats) for recording of corrective actions, harvest termination, planting, post-harvest monitoring, spatial isolation, storage inspection, transport and storage. An accidental release of GEp into environment occurring during any stage of crop growth is required to be reported immediately via telephonic conversation and in written document within 24 hr of the accident. Remedial actions should be taken against such accidents by the permitted party under guidance of RCGM/GEAC.

Assessment of risk related to food and feed and environment

Risk is product of size of hazard and probability of occurrence of hazard (46). Risk assessments are conducted to collect information on possible factors which can manifest into threat in future and to formulate measures to overcome probability of occurrence of threat. Potential risks in CFTs can be alleviated by following spatial or reproductive isolation; termination of any unwanted GEp plant or its progeny after harvesting; and by preventing any accidental release of GEp into human or animal food chain. Based on data collected from the CFT trial, risk assessment of GEp as food, feed and potential threat to ecology and environment is assessed (47, 48).

These trials help plant breeders assess agronomic potential in open environments, like conventional breeding trials. They also measure protein expression levels in various plant tissues to predict dietary exposure to humans and livestock. Additionally, they provide plant material for livestock feeding trials and compositional analyses needed for food safety assessments. Furthermore, confined field trials gather essential agronomic and ecological data for environmental safety evaluations, including studies on non-target insects and the environmental impact of novel plants (35, 45). A detailed description of safety assessment of different parameters studied is given in Table 5.

An oversee of implementation of confined field trials in India (42)

To conduct a CFT, the applicant is required recommendation from IBSC. Institutional Biosafety Committee is a committee established at institution level to administer transgenic related research work. Institutional Biosafety Committee examines the application on DBT guidelines and recommends RCGM. Now, RCGM works out risk assessment and device various alleviating ways to overcome any risk situation. Once an application is recommended by IBSC,

then the applicant can apply for CFT application to RCGM and GEAC depending on type of biosafety concerned with the specific trial; viz., RCGM and GEAC look after BSL I and BSL II respectively (Fig. 1). However, the environmental release of new event (GE crop or product) is allowed only after research and data collected for 3 crops seasons of CFT: BSL I in first crop season; BSL I or BSL II in second crop season and BSL II in third crop season.

National and International regulations on genetically engineered organism (plant/animal/microorganisms): India, United States and European Union

National food safety regulatory system of countries, most of the countries in the world, have their own GMO regulation authorities. Likewise in India, use of GEp or its products are administered under “Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells” notified under the Environment (Protection) Act, 1986; i.e., Rules, 1989. Several Acts, rules, Ministries of India (Table 6) and committees work in synergy to regulate the whole GE related study/release of GMO/framing rules etc. The responsibility of proper enforcement of these rules and laws is supervised by Ministry of Environment and Forests (MoEF) and Department of Biotechnology (DBT) and State Governments (42, 44). Six principal committees have been formed with their respective allocated mandates and functions to regulate GMO in India (44, 49). The organised consortium of ministries and committees handles four responsibilities: a) executory- DBT, MoEFCC and state governments; b) advisory: Recombinant DNA Advisory Committee (RDAC); c) regulatory: RCGM, GEAC, IBSC; d) monitoring: SBCC and DLC. A detailed description of all committees their role is mentioned in Fig. 2 and Table 7.

Regulatory framework for GMO regulation in European Union (EU) is stringent, extensive and transparent to assure protection of health (human/animals) and environment. The legislations of GMO regulation in EU are derived from multiple statutes, mentioned below (50–52):

- **EU Directives 2001/18/EC**– Conscious release of GMO into environment (except placing GE plants in market).
- **Regulation (EC) 1829/2003**– Regulate cultivation of GE plant and feed present in EU market
- **Regulation (EC) 1830/2003**– Ensures traceability and labelling of GMO used as food and feed.

Table 5. Safety and risk assessment of genetically engineered plants

Parameters on which data is recorded	Safety assessment of food and feed		Risk assessment of environmental and ecology	
	Field studies	Non-field studies	Field studies	Non-field studies
Acute or safety limit of oral intake	x	✓	X	X
Pepsin digestibility assay	X	✓	X	X
Protein thermal stability	X	✓	X	X
Sub chronic feeding study in rodents	X	✓	X	X
Livestock feed	✓	X	X	X
Molecular analysis	X	✓	X	✓
Inheritance of genetically engineered trait	✓	X	✓	X
Stability of introduced trait	✓	X	✓	X
Expression of genetically engineered protein	✓	X	✓	X
Compositional analysis	✓	X	X	X
Reproductive and survival biology	X	X	✓	X
Impact on environment and ecology	X	X	X	✓
Impact on environment and ecology	X	X	✓	X

✓ conducted; X not conducted.

Table 6. The six main committees and their roles in regulation of genetically modified organism in India (44)

Committee	Role	Function under
RDAC (Recombinant DNA Advisory Committee)	- Assessment of biotechnological development at national and international levels - Advocate appropriate safety rules and regulations in recombinant research field - Frame and amend policies for R&D in recombinant research field	DBT
RCGM (Review Committee on Genetic Manipulation)	- Monitor practices of safety rules and regulations in recombinant DNA research - Frame protocols to forbid any unwanted or illegal production import export or sale of GE organism/crop - Draft manuals and guidelines for the safer utilisation of GE organism in research to prevent any adverse impact on human, animal and environment - Issue permit letter for import or exchange of recombinant DNA (gene, DNA fragment, vector, plasmid etc.) - Examining CFTs applications - Power to authorise an applicant to carry out his/her research related to GMO on case-by-case basis - Conduct training courses on biosafety - Appointing experts on case-by-case basis - Form subgroups, sub-committees for the proper functioning viz., research lab/sites visit, ensure practice of all guidelines and SOPs in CFT or research labs - Maintain confidential information given by the applicant - Working time period from the date of notification: 3 years - Conduct Meeting once a month - Form Monitoring cum Evaluation Committee (MEC)	DBT
IBSC (Institutional Biosafety Committee)	- Implement Biosafety rules, SOPs and guidelines - Ensure that the institution undertaking research in recombinant field is following biosafety rules scrupulously - Members: Head of the institution, scientist engaged in the recombinant DNA work, a medical doctor and a DBT nominee - Make report and approve the Category I/II level of genetic engineering work	DBT
GEAC (Genetic Engineering Appraisal Committee)	- Approve use biohazardous micro-organisms/GE organisms or cells in academic research or industrial production - Approval of CFT, release of GE organism or GE crop or product in environment	MoEF&CC
SBCC (State Biotechnology Coordination Committee)	- Take actions in case of violation under State Pollution Control Board (SPCB) OR Directorate of Health etc. - Monitor safety measures undertaken at different institutions involved in recombinant DNA related study or production - In case of any accidental breach of biosafety guidelines make damage, assessment and impose control measures	State government
DLC (District Level Committee)	- Monitor safety regulations in biohazardous organisms of the concerned institution in the district - Work out an information chart, off-site emergency plan - Risk analysis - Submit report to GEAC/SBCC after monitoring the concerned institution at regular intervals	District Collector

Table 7. A comparative illustration of regulation of genetically modified organisms in India, EU and USA (44, 52, 53)

Features	India	European Union (EU)	USA
Source of Legislation	Environment Protection Act, 1986. Guidelines for Research in Transgenic Crops, 1998	Several Directive and Regulations formulate by election commission (EC)	Coordinated Framework for Regulation of Biotechnology, 1986
Regulatory approach	Case-by-case basis	Process	Product
GE approval authority/body	GEAC	EFSA, EC, PAFF	USDA, EPA, FDA
GM crops in commercial cultivation	Very limited	Limited cultivation	Widely cultivated
Labelling	Stern labelling	Stern labelling	Facile labelling

GEAC: Genetic Engineering Appraisal Committee; EFSA: European Food Safety Authority; EC: European Commission; PAFF: Standing Committee on Plants, Animals, Food and Feed; USDA: United States Department of Agriculture; EPA: Environmental Protection Agency; FDA: Food and Drug Administration.

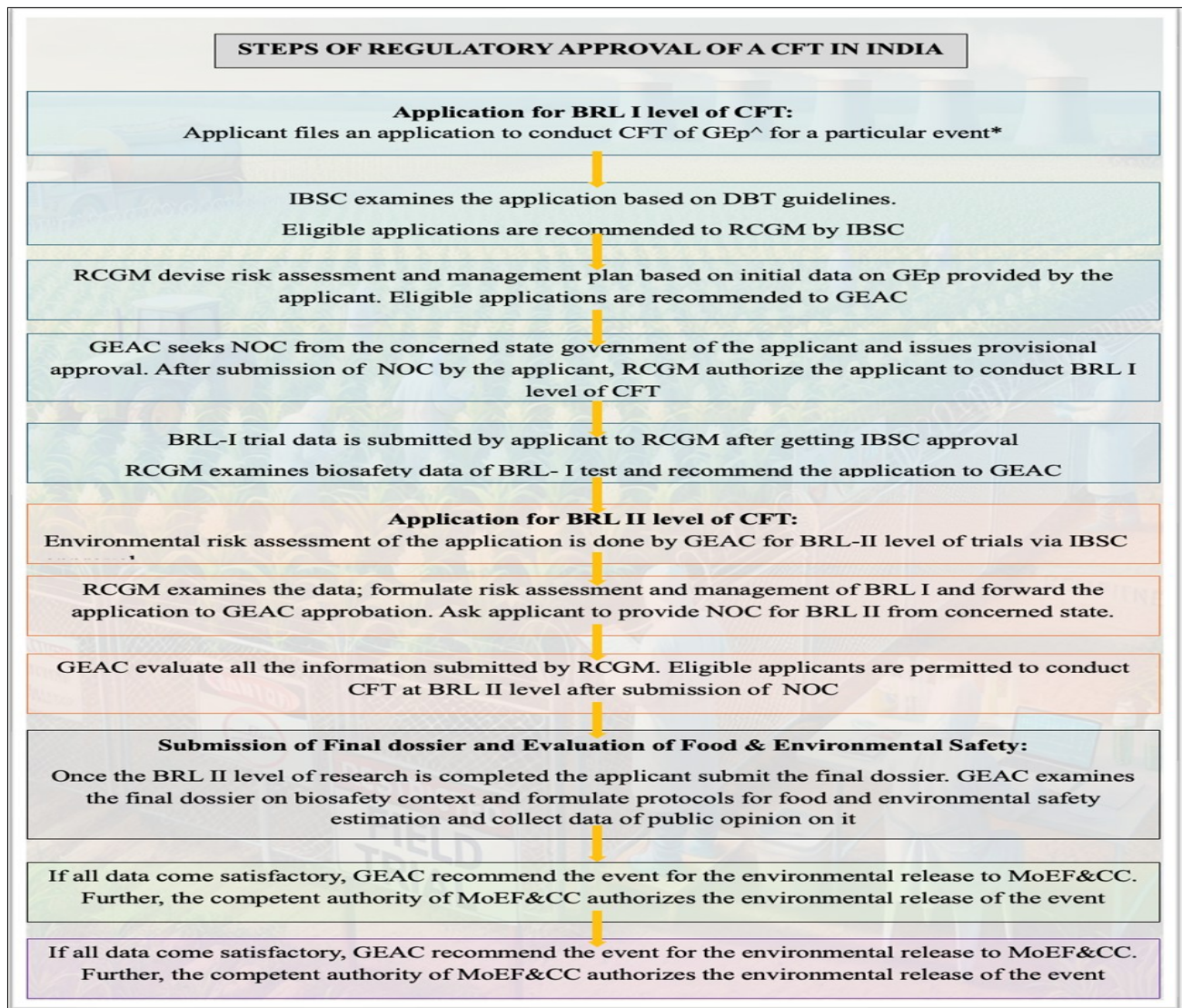
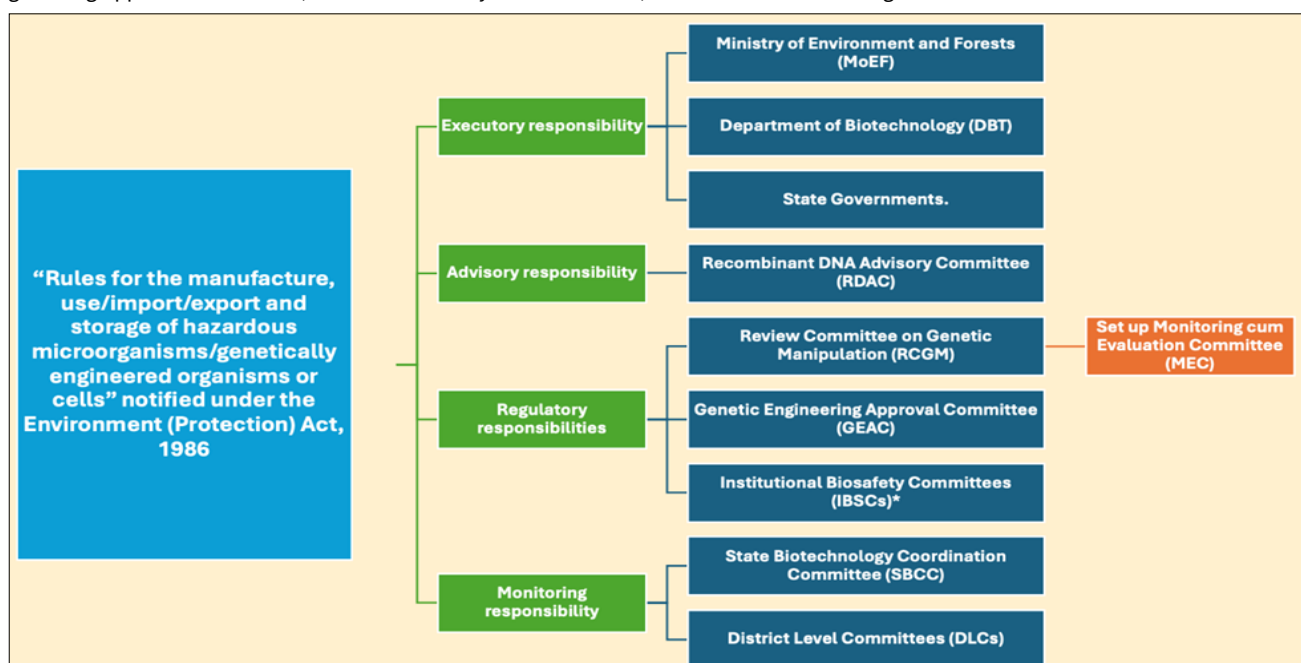


Fig. 1. Steps of regulatory approval of confined field trails in India. Adapted from IBSC Handbook (<https://ibkp.dbtindia.gov.in/Content/FlashPDF/IBSC%20Handbook.pdf>) Event*: Genetically engineered or transformed genotype of a plant species (single) developed using a foreign gene/DNA construct. GEp*: Genetically engineered plant CFT: confined field trials; GEp: genetically engineered plants; DBT: Department of Biotechnology; RCGM: Review Committee on Genetic Manipulation; IBSC: Institutional Biosafety Committee; GEAC: Genetic Engineering Appraisal Committee; MoEF&CC: Ministry of Environment, Forest and Climate Change.



Source: http://www.geacindia.gov.in/resource-documents/13_2-Regulatory_Framework_for_GE_Plants_in_India.pdf

Fig. 2. Schematic representation of regulation of confined field trails in India.

- **Directive 2009/41/EC**– Monitor contained used of GE microorganism in laboratories, research facilities and its uses in industrial production
- **Regulation (EC) 1946/2003**– Monitors export/import of GE organism on principles of Cartagena protocol.
- **Regulation (EC) 258/97**– Safety assessment of novel food and novel food ingredients.
- **Directive (EU) 2015/412**– “*opt out directives*”: under this all the EU members are free to restrict or prohibit the GMO cultivation in their territory.
- **Regulation (EU) 503/2013**– Deals on application for authorisation of GE food or feed in compliance with Regulation (EC) 1829/2003.
- **GMO register**– A search engine, that is collection of Community register of GM food and Feed under Regulation (EC) 1829/2003.

Several regulatory bodies administer the regulation of GMO in EU. 1) European Food Safety Authority (EFSA)- monitors scientific risk assessment; 2) European commission along with EU parliament- undertake the legislation function; 3) National competent Authority- performs the role of monitoring and enforcement of legislations; 4) European Union Reference Laboratory for GMO Regulation (EURL-GMFF)- validates the GMO detection methods; and 5) Standing committee on Plants Animals food and Feed (PAFF Committee)- votes for GMO authorisation.

Likewise, in USA, GEp are regulated by the Biotechnology Science Coordinating Committee that consists of three federal agencies viz., EPA, USDA and FDA (52, 53). While the legislation comes from Plant Protection Act; Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA); and Federal Food, Drug and Cosmetic Act (FFDCA) (54). FDA mandates biotechnologically derived medical products (54); USDA supervises transgenic crops (54) while, the EPA mandate is pesticidal plants and GE microbial pesticide) (54).

FDA, USDA and APHIS primarily regulate GEp research, trials and introduction into market. However, no labelling viz., GMO or Non-GMO has been introduced by FDA. On safety issues of GMO, EPA and FDA had different views as before 2022 FDA didn't label food based on method of its production unless there were any safety concerns. On safety parameters, GM foods were considered equivalent to conventional foods in USA (55). CFT or field trials for GEp are conducted in USA, under the guidance of USDA (55). Office of Science and Technology Policy (OSTP) regulate all the responsibilities to the regulatory agencies engaged in GE organisms in USA viz., FDA, USDA and EPA (56). FDA issues 'memo' on safety of a GEp as food or feed that GEp to be used as food or feed is as safe as its non-GE crop counterpart (57).

World Trade Organization (WTO), Cartagena protocol and Codex Alimentarius are the international regulatory bodies for GMO including GEp (57). Technical Barrier to Trade (TBT) agreement of WTO encourages protocols employed for equitable technical regulations (58), standards and assessment protocols, to avoid any barrier in international trade (58). Sanitary and Phytosanitary (SPS) agreement of WTO supervises member nations to secure food safety of plants and animals. It encourages nations to devise their own measure according to international

guidelines, standards and recommendations to prevent disease spread in animals and plants (58).

Cartagena protocol addresses issues related to export/import of GEp. It has introduced advanced information agreement (AIA) under biosafety protocol to allow full disclosure, labeling of GEp to be exported/imported. The AIA enables assessment of potential environmental risk of import/export of GEp (59).

Biosafety protocol: Adoption of precautionary principle under which importing country of GEp has right to deny importing a GEp material if do not ensure to be safe (59).

Supplementary protocol on Liability and Redress addresses the consequences of uses of GMO as food, feed or its impact on environment (60). The protocol focuses on formulating remedies for the damage caused due to LMO.

Codex Alimentarius Commission (CAC) regulates GMO by a) assessment of risk b) management of risk and c) communication of risk. The CAC issue guidelines for food safety regulation (61) and risk analysis of food (62) on scientific basis.

Conclusion

In the field of research and development of genetically engineered plants (GEp), confined field trials (CFT) play crucial role being an integral part of process of genetically modified organism (GMO) regulation. Confined field trials assist in comprehensive study of the phenotypic and genetic expression of the introduced gene of the GEp. Consequently, extensive data are being collected following stringent rules of CFTs under regulatory bodies viz., Institutional Biosafety Committee (IBSC) at institution level to Genetic Engineering Appraisal Committee (GEAC) at ministry level in India and equivalents regulatory bodies of other countries (e.g., USDA in USA). Confined field trials and non-GMO field trials can be analogical to each other; yet different as the former is regulated under preeminent level of biosafety regulations, regulatory bodies while for later no such regulations are mandatory. The amount of information collected from CFTs assist in study of GEp impact on environment, non-targets (pests/pathogen/weed) and as food or feed. These trials provide scientific evidence to substantiate the safety of GMOs to common public. Confined field trials is an experimental trial conducted for GEp in confined area following guidelines and regulated under different rules acts, committees and ministries of India, directive and regulations in European Union (EU) etc. Confined field trials assure transparency and scientific credibility. The efficient implementation of legislation and regulations formatted in different countries can fortify GMO to overcome the controversies surrounding it and allow common people to benefit from its potential use. Proper execution of CFT can lead to one step closer to collecting enough scientific data to substantiate the data of GMO to common people and scientific community. Confined field trials are crucial for the scientific, political and social acceptance of transgenic crops and are a prerequisite for the general environmental release of GEp.

Authors' contributions

The manuscript was prepared with valuable contributions from all authors. The study was conceptualized by AS¹. Literature collection was carried out by MS, MK¹ and AS¹. The manuscript

was drafted by AS², MK² and AA. Overall guidance in writing the manuscript was provided by MS and MK¹. All authors have read and approved the final manuscript [AS¹: Aarti Sharma and AS²: Aradhana Suman; MK¹: Manish Kumar and MK²: Mahesh Kumar].

Compliance with ethical standards

Conflict of interest: Authors do not have any conflict of interest to declare.

Ethical issues: None

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