Agri Articles
(e-Magazine for Agricultural Articles)
Volume: 04, Issue: 04 (JULY-AUG, 2024)
Available online at http://www.agriarticles.com
©Agri Articles, ISSN: 2582-9882

Management and Regulation of Biosafety Issues Related to Genetically Engineered Crops

(*Shubham and Hitesh)
Department of Genetics & Plant Breeding, CCS Haryana Agricultural University, Hisar
*Corresponding Author's email: shubham27lb@gmail.com

Transgenic/Genetically Engineered Plant

A transgenic plant is a normal crop plant with one or more additional genes from diverse sources engineered into the plant genome; the plant thus acquires new, stable and inherited traits.

Biosafety issues in transgenic crops

Biosafety is protecting human and animal health as well as biodiversity from the possible adverse effects of the products of modern biotechnology (Kumar, 2015). Transgenic or genetically engineered crops may have immediate or long-term negative effects on the environment. Biosafety risks involve the entire spectrum of biodiversity and a universal 'true for all' approach may not be applicable. Some issues related to GE crops are:

- Transfer of allergens and toxins from one life form to another and creation of new toxins and allergenic compounds
- Development of aggressive weeds/ wild relatives by transfer of transgenic traits
- Erosion of landraces/wild relatives by genetic pollution in centers of origin/ diversity
- Harm to the non-target organisms
- Development of pest resistance by prolonged use
- Monoculture and limitations to farmer's choice in crop management
- Hazard to human and animal health by transfer of toxins and allergens and by creation of new toxins and allergenic compounds.

Management of biosafety issues

Biosafety issues are managed at two stages:

1. Laboratory stage 2. Confined Trial Stage

1. Laboratory/greenhouse stage: It refers to laboratories/greenhouses in which physical containment of highly pathogenic organisms or genetically engineered organisms is required, usually by isolation in environmentally and biologically secure cabinets or rooms, to prevent accidental infection of workers or release into the surrounding community during scientific research. Different biosafety levels as per the degree of risk involved.

Can GE plants evaluated in the greenhouse only? Data that 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 as it is virtually impossible to comprehensively replicate the outdoor environment in a greenhouse. Greenhouse studies are useful only in the initial stages as these are conducted in a controlled environment and are inadequate to predict how a plant will perform when grown outdoors under natural environmental conditions.

Biosafety levels: Level of the biocontainment precautions required to isolate dangerous biological agents in an enclosed facility. The levels of containment range from the lowest biosafety level 1 to the highest at level 4.

a. **Biosafety level 1:** It is suitable for work involving well-characterized agents not known to consistently cause disease in humans. It has minimal potential hazard to laboratory personnel and the environment.
b. **Biosafety level 2:** It is suitable for work involving agents of moderate potential hazard to personnel and the environment. It includes various bacteria and viruses that cause only mild disease to humans or are difficult to contract via aerosol in a lab setting. Genetically engineered organisms have also been classified as level 2 organisms, even if they pose no direct threat to humans. This designation is used to limit the release of engineered organisms into the environment.
c. **Biosafety level 3:** This level is applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease after inhalation. It includes various bacteria, parasites and viruses that can cause severe to fatal diseases in humans but for which treatments exist.
d. **Biosafety level 4:** This is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections. It includes agents that cause severe to fatal disease in humans for which vaccines or other treatments are not available. When dealing with biological hazards at BSL 4 the use of a Hazmat suit and a self-contained oxygen supply is mandatory.

2. Confined Trial Stage: Confined field trials (CFTs) are small-scale field experiments to address biosafety requirements and evaluate the performance of specific traits in genetically engineered (GE) plants. These are similar to field experiments done for conventional breeding, but they are confined. The release of a transgenic plant species for research purposes is conducted under conditions that prevent the spread of the organism and mitigate its impact on the surrounding environment.

Stage at which CFTs are conducted

- Scientists investigate potential beneficial traits, identify genes and carry out genetic transformations in research labs and green-houses (contained conditions).
- For advancing research, confined field trials (CFTs) are conducted in a real-life environment.Safety assessment studies are undertaken to secure regulatory approval in the country where the plant will be grown and its products consumed by humans or animals. The final step is commercial production.

Types of CFTs

1. **Selection Trials:** Small plots are used for assessments of various crop genotypes for field trails. Selection is done as per performance then further safety evaluation is done.
2. **Biosafety Research Level Trials (BRL-I):** Limited in size to no more than 1 acre per trial site location and a maximum cumulative total of 20 acres for all locations for each plant species, per Applicant, per crop season.
3. **Biosafety Research Level - II Trials (BRL-Il):** Limited in size to no more than 2.5 acres 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.
4. **Experimental Seed Production:** Production of seeds for the selected events under confined field trial conditions for the next phase of trials.
5. **Production of plant material for food and feed safety studies**: To generate plant material for undertaking various food and feed safety studies such as toxicity and feeding studies under confined field trial conditions.

6. **Other environmental safety studies**: Trait or crop specific studies under confined field conditions for generating data on environmental safety e.g. residue analysis, cross-ability studies etc.

Guiding Principles for Confinement

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

I. Material Confinement
II. Genetic Confinement
III. Post-Harvest Land Use Restrictions

I. Material Confinement

It is done to maintain control of the GE plant material at all times to prevent eating by humans or livestock and mixing it with non-GE material. Measures undertaken to ensure material confinement include:

- Appropriate packaging and labelling og material for transport to and from the trial site to secured storage and measures for cleaning and disposing of the packaging material.
- Cleaning of all equipment used for various activities during the trial, so that no propagative plant material remains viable.
- All the plant material generated during the trial, except that authorized by regulatory authorities to be retained for safety studies/further research, to be disposed off by incineration, burying on the trial site, crushing or chemical treatment.
- To ensure security of the trial site to prevent incursion by humans or animals, measures include fencing, security guards, lockable gates etc. on a case by case basis.

II. Genetic Confinement

It is done to prevent any pollen-mediated gene flow from the trial sites. Different methods are used in CFTs to achieve genetic confinement also referred to as reproductive isolation. These methods help to prevent pollen dispersal or prevent fertilization to ensure genetic confinement.

a) **Spatial Isolation:** Spatial isolation by maintaining a minimum isolation distance prescribed by the regulatory authorities, which are based on accepted distance for pure seed production under Indian Minimal Seed Certification Standards.
b) **Pollen Trap Rows**: Field trials of GE plants may be reproductively isolated from the same or related species by planting uninterrupted perimeter borders of the conventional plant species referred as pollen trap rows or border rows which attract insects and reduce pollen flow.
c) **Early Termination:** Early termination is destruction of the trial plants prior to anthesis and pollen shed which helps in reproductive isolation.
d) **Artificial Barriers:** Reproductive isolation may also be achieved by placing physical barriers such as screening material around the trial plants, also referred to as tensing. Such material should be of a mesh size sufficient to prevent the transfer of pollen.

III. Post-Harvest Land Use Restrictions

It is done to prevent persistence by maintaining control of CFT sites in the following years/season by eliminating volunteers. Progeny arising from the GE plants at the field trial site are known as 'volunteers', and must be prevented from establishing and flowering after termination of the trial. The area under restriction must be monitored during the post-harvest period to ensure that any prohibited plants (volunteers or sexually compatible species) are destroyed before flowering. The post-harvest restriction period begins immediately upon final harvest or termination of the CFT at trial site. If any prohibited plants are permitted to flower, the post-harvest restriction period will be extended by an additional term equal to the original post-harvest restriction period. Monitoring for and destruction of prohibited plants also

applies to the isolation distance around the trial site if reproductive isolation was breached during the trial.

Regulation of CFTs of GE Plants in India

CFTs 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. The regulatory steps followed for approvals are as follows:

- The initial assessment of an application for CFT begins at the institutional level itself. Application to Institutional Biosafety Committee (IBSC) is based on information generated by the applicant in lab/greenhouse and on preliminary phenotypic evaluation.
- If recommended by IBSC, an application in the prescribed format along with information on experimental design and details of data to be generated is submitted to Review Committee on Genetic Manipulation (RCGM). RCGM is the regulatory authority for BRL-I trials (size limited to no more than one acre per trial site location).
- Genetic Engineering Appraisal Committee (GEAC) is the regulatory authority for BRL - Il trials (size are generally limited to no more than 2.5 acres/trial site location). The number of locations for BRL-II trials is decided on case by case basis for each plant species/gene combination, per applicant per crop season.
- No person can establish a CFT of any GE plant in India without the prior approval of RCGM and GEAC under Rules, 1989. Minimum of three seasons/year's CFTs are required for consideration of an application by GEAC for release of an event, which generally consist of two years/seasons of BRL-I and one year/season of BRL-II scientific evaluation.

Safety Assessment Requirements Prior to Conduct of CFTs

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 regulatory systems permit the confined field evaluation of GE plants.

Monitoring/inspection of CFTs

- As the trial is done with plants that are 'regulated', or not yet approved for general release, the Regulatory Authority maintains oversight of the trial, through periodic inspections on the progress and compliance of the trial.
- Each field trial is monitored by a Central Compliance Committee (CCC) constituted for a specific authorization on a case by case basis. The CCC consists of subject-specific experts, representatives from RCM/ GEAC, representative from state agriculture department and state agricultural universities.
- Monitoring is undertaken at various stages during the conduct of confined field trials. These include pre-sowing, sowing, and various stages of crop development, harvest and during the period of post- harvest land use restriction.

Conclusion

The development of a genetically engineered (GE) plant in research laboratories has to be progressively tested in contained facilities such as greenhouses and field conditions before its commercialisation. The information and data collected during these trials is critical for assessing agronomic performance as well as biosafety assessment required by the regulatory authorities. From the regulatory standpoint, the terms and conditions governing CFTs include

a combination of science-based confinement measures together with a system of adequate monitoring. This provides an overview of the concepts and scientific principles of reproductive isolation and other effective risk mitigative measures adopted to minimize adverse impacts on the environment during confined filed trials. CFT trails introduces the role that such trials play in both the product development pipeline and the regulatory review process.

References

1. Confined Field Trials of Genetically Engineered (GE) Plants, 2015. http://www.geacindia.gov.in/resource-documents/13_4-Confined_Field_Trials_of_GE_Plants.pdf
2. Kumar, S. (2015). Biosafety and biosecurity issues in biotechnology research. *Biosafety*, **4**(01): 153.