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A PRIMER FOR FARMERS

Regulation of Genetically Modified Crops

Prepared under

gef UNEP

Phase-II Capacity Building Project on Biosafety

Ministry of Environment
Forests and Climate Change

Ministry of Environment
Forests and Climate Change
Government of India

In association with

BCIL
Biotech Consortium India Limited
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Ministry of Environment, Forest and Climate Change (MoEFCC) and
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under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety

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Introduction

Farmers have relied on selective breeding and cross fertilization for thousands of years to impart desirable traits in plants such as higher yields and resistance to pests. Plant varieties have been developed with altered and stable genetic traits through trial and error. The advent of genetic engineering techniques allows precise manipulation of the intricate genetic structure of individual living cells by incorporating genes from different species. The resulting organisms are known as genetically modified organisms (GMOs) or living modified organisms (LMOs). When the GMO is a crop plant, it is called a GM crop or transgenic crop.

In most cases, the aim is to introduce a new trait to the crop such as pest resistance, disease resistance, herbicide tolerance, improved product quality etc. Several GM crops viz. cotton, canola, maize, soybean, papaya, etc. have been developed and cultivated. The first crop was introduced in 1996, since then the global area under cultivation of GM crops has increased to 185 million hectares in 2017.

Bt cotton is the only GM crop approved for cultivation in India. Bt cotton, first grown in 2002 now occupies more than 90% of cotton area in the country. It is grown on approx. 11 million hectares. Several more crops such as chickpea, pigeonpea, corn, sugarcane, etc. are in various stages of research and field trials. These differ depending on gene crop combination. In view of the above, biosafety regulatory framework have been put in place by countries to ensure that GM crops are as safe as conventional crops.

In India, GM crops are regulated as per Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells (Rules, 1989) notified in 1989 under Environment (Protection) Act, 1986. All the steps in the development of GM crops viz. laboratory research, greenhouse/ nethouse studies, confined field trials and safety studies are regulated before granting permission for environmental release. The regulatory committee functions under the Ministry of Environment, Forest and Climate Change (MoEFCC), Department of Biotechnology (DBT) along with state governments.

MoEFCC being the nodal ministry for biosafety regulations of GM crops has implemented the Phase II Capacity Building Project on Biosafety with support from Global Environment Facility (GEF) through the United Nations Environment Program (UNEP), to strengthen the biosafety management in India. 'Enhancing Public Awareness' is one of the key thrust areas of the project. Significant efforts have been made to ensure outreach through multiple tools viz workshops, printed materials, short films, etc.

In continuing with the same, MoEFCC in association with Biotech Consortium India Limited (BCIL), the Project Coordination Unit has prepared booklet for specific categories of stakeholders focusing on their information requirements.

This handbook has been prepared to inform farmers about the key aspects of GM crops. It has the following five sections:

1. Development of GM crops
2. Status of GM crops
3. Biosafety regulations
4. Confined field trials
5. Detection of GM crops

Section 1: Development of GM crops

Genetic modification involving the copying and transfer of genes from one organism to another is possible because the genetic code is universal i.e. the DNA[1] of all organism is made up of the same building blocks and is encoded in exactly the same way. Therefore, it is possible to transfer a copy of DNA sequence (or gene[2]) that codes for a particular characteristic into the cell of a different organism. Once the gene is incorporated into the genome of recipient, the resulting organism is considered to be genetically modified and the new characteristic coded by that gene is inherited by subsequent generations.

The steps involved in the development of a GM crop are as follows:

a. Identification of a gene(s) giving a desired trait
b. Designing genes for insertion
c. Transfer to plant tissue
d. Selection and regeneration of plants
e. Lab analysis and safety testing
f. Greenhouse and field trials
g. Approval by Government agencies
h. Commercialization
i. Monitoring of efficacy and safety

Genetic engineering or transgenic technology is similar to conventional breeding in terms of objective of generating more useful and productive crop varieties containing new combinations

[1]DNA: Deoxyribonucleic acid, more commonly known as DNA, is a complex molecule that contains all of the information responsible for the inheritance of traits such as size, shape, color, build and other physical attributes of microorganisms, plants, animals and humans. DNA exists in the nucleus of each cell.

[2]Gene: A gene is basically a discrete segment of DNA encoding for set of instructions in the cell and contains all information concerning the form and functions of all living cells that give characteristics to an organism.

of genes, but it expands the possibilities by enabling introduction of useful genes not just from within the crop species or from closely related plants, but from a wide range of other organisms. It allows the transfer of one or more genes, in a controlled and predictable way than is achievable through conventional breeding as depicted in the Figure 1.

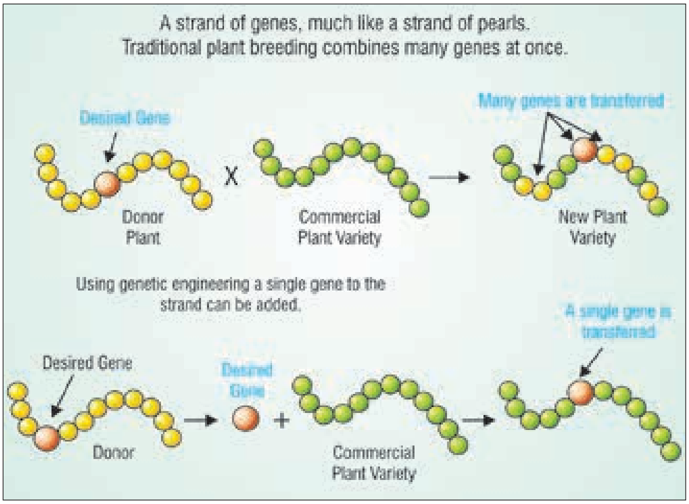


Fig 1: Traditional Plant Breeding vs Genetic Engineering

Although objectives of both the techniques are same, there are some technical differences between both the techniques which make genetic engineering preferable. Differences between two techniques are given in Table 1:

Table 1: Comparison between plant breeding and genetic engineering

S. No.	Plant breeding	Genetic engineering
1.	Exchange of genes within a species	No barrier
2.	Gene of interest along with flanking sequence transferred	Only gene of interest transferred
3.	Simple technology	Intensive technology
4.	History of safety	New technology; safety assessment required

The GM crops have been developed to incorporate various traits such as insect/pest resistance, herbicide tolerance, disease resistance, altered nutritional profile, enhanced storage life etc. The benefits may include:

- higher crop productivity due to reduced loss to pests and diseases,
- reduction in farm costs and thereby increase in farm profit,
- general improvement in health and environment due to availability of nutritionally enhanced food,
- reduced use of pesticides/ insecticides in the environment which would further reduce the fuel consumption and also led to preservation of natural resources like soil and water due to decreased tillage, and
- improved weed control due to use of herbicide resistant GM crops.

Potential benefits of various traits incorporated in the GM crops are summarized in Figure 2.

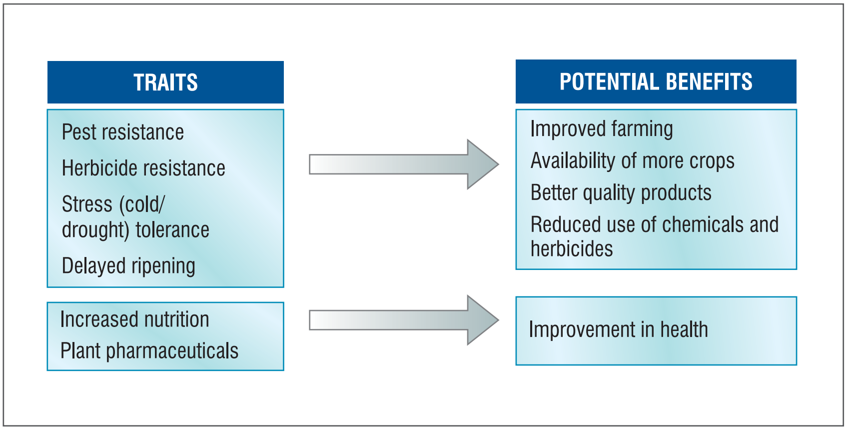


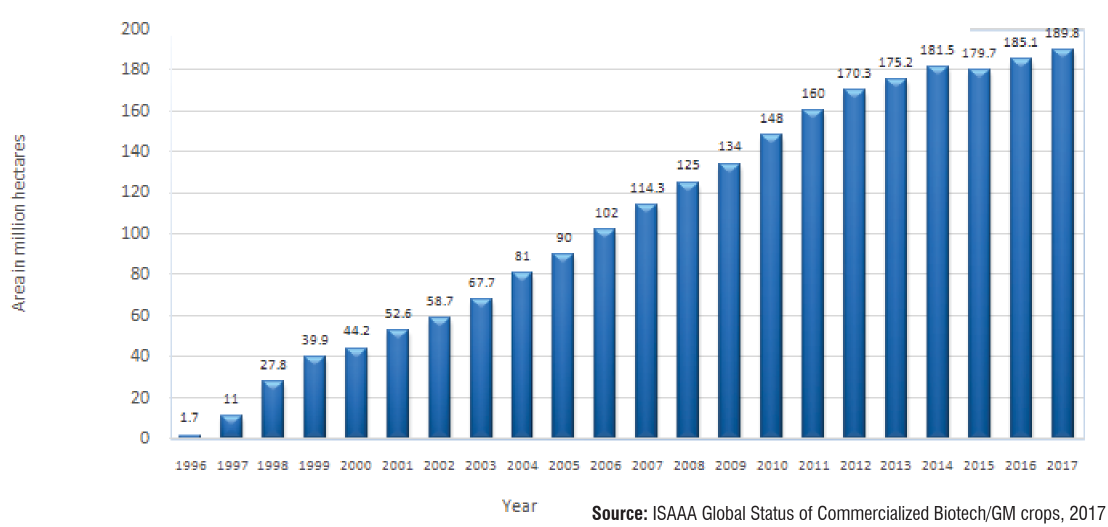
Fig 2: Potential benefits of GM crops

Section 2: Status of GM crops

Plants that have been subjected to genetic improvement for multiple traits include several commercially important crops such as maize, soybean, tomato, cotton, potato, mustard and rice; horticultural plants such as papaya, plum; grasses such as alfalfa; and trees such as poplar. Most common traits so far include insect resistance and herbicide tolerance. Other traits of interest include virus resistance, fungal resistance, high nutritional value, improved product quality etc.

Global Status

The area under cultivation of GM crops has increased from 1.7 million hectares in 1996 to 189.8 million hectares in 2017 grown by over 17 million farmers, globally (Figure 3). Out of 24 countries that planted GM crops, in 18 countries the area under GM crops was 50,000 hectares or more. Five countries with highest acreage include USA, Brazil, Argentina, Canada and India



Source: ISAAA Global Status of Commercialized Biotech/GM crops, 2017

Fig 3 : Global Area of Biotech Crops, 1996 to 2017

The list of GM crops, traits and countries where they are approved for cultivation is given in Table 2 below:

Table 2: Status of cultivation of GM crops in various countries in 2017

S.No.	GE Plants	Traits/Uses	Countries where approved
1	Alfalfa	Herbicide tolerance	USA
2	Apple	Anti-bruising and anti-browning	USA
3	Beet pepper	Virus Resistance	China
4	Canola	Herbicide tolerance and improved protection against weeds	Canada, USA, Australia, Chile
5	Carnation	Modified flower colour and herbicide tolerance	Australia, Columbia
6	Cotton	Improved insect protection, herbicide tolerance and improved protection against weeds	Australia, USA, China, Mexico, South Africa,
7	Egg Plant (Brinjal)	Insect resistance	Bangladesh
8	Maize	Improved insect protection and herbicide tolerance for efficient weed management.	Canada, USA, Argentina, Brazil, South Africa, Uruguay, Philippines, Chile, Columbia, Honduras, Spain, Portugal, Paraguay, Cuba, Czech Republic, Romania, Slovakia
9	Papaya	Virus resistance	USA, China
10	Petunia	Modified flower color	China
11	Poplar	Insect resistance	China
12	Potato	Improved quality, anti-bruising and anti-browning	USA
13	Soybean	Improved insect protection and herbicide tolerance for efficient weed management.	USA, Argentina, Canada, Paraguay, Mexico, Bolivia, Brazil, Chile, South Africa, Romania, Uruguay, Costa Rica
14	Squash	Resistance against watermelon mosaic virus and zucchini yellow mosaic virus	USA
15	Sugar beet	Herbicide tolerance	USA and Canada
16	Tomato	Delayed Ripening, Virus resistance	China

Source: ISAAA Global Status of Commercialized Biotech/GM crops, 2017

An additional 43 countries have granted regulatory approvals for GM crops for import as food and feed use. These include major food and feed importing countries like Japan, South Korea and European Union.

Status in India

To date, Bt cotton is the only GM crop approved for commercial cultivation in India. The total area under Bt cotton has increased from 0.05 million hectares in 2002 to 11.4 million hectares in 2017 (Figure 4). As of now, Bt cotton is cultivated in more than 90% of the area under cotton cultivation in India. In terms of area under cultivation of GM crops, India is fifth in the world after USA, Brazil, Argentina and Canada.

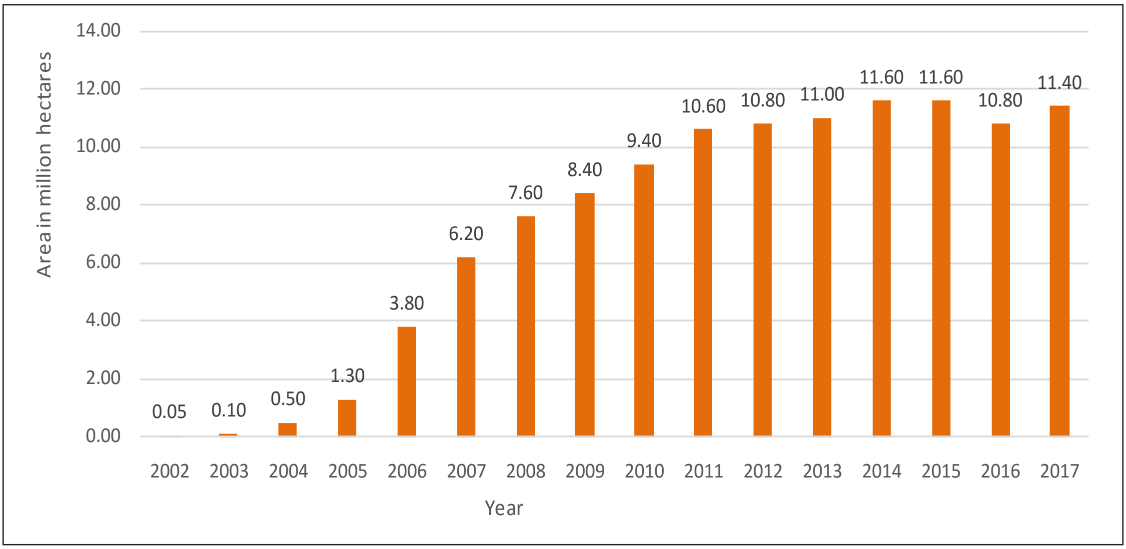


Fig 4: Area under Bt cotton cultivation in India

Several public and private sector institutions are involved in the research and development of GM crops in India (Table 3). Field trials have been undertaken with more than 20 plants with varying traits such as hybrid seed production, insect resistance, herbicide tolerance etc.

Table 3: An indicative list of GM crops under research and development/ field trials in India

S. No.	Plant	Trait
1.	Banana	Antimicrobial peptide (AMP) gene
2.	Brinjal	Insect resistance
3.	Cabbage	Insect resistance
4.	Castor	Insect resistance
5.	Cauliflower	Insect resistance
6.	Chickpea	Abiotic stress tolerance, insect resistance
7.	Corn	Insect resistance, herbicide tolerance
8.	Cotton	Insect resistance, herbicide tolerance
9.	Groundnut	Virus resistance, abiotic stress tolerance
10.	Mustard	Hybrid seed production
11.	Okra	Insect resistance
12.	Papaya	Virus resistance
13.	Pigeonpea	Insect resistance
14.	Potato	Tuber sweetening, fungal resistance
15.	Rice	Insect resistance, diseases resistance, hybrid seed production, nutritional enhancement
16.	Rubber	Abiotic stress tolerance
17.	Sorghum	Insect resistance, abiotic stress tolerance
18.	Sugarcane	Insect resistance
19.	Tomato	Insect resistance, virus resistance, fruit ripening
20.	Watermelon	Virus resistance
21.	Wheat	Effect of mutant strains Azotobacter

According to a survey conducted by MoEFCC in 2014 under the UNEP-GEF supported Phase II capacity building project on biosafety, over 85 different plants species were identified as being used in experimental work, including plants used for food, feed, fiber, fuel and dietary or medicinal purpose.

Section 3: Biosafety regulations

All GMOs including GM crops are regulated in India under the Rules for the Manufacture/ Use/ Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (Rules, 1989), notified under the Environment (Protection) Act, 1986. The Rules, 1989 are very broad in scope, essentially covering entire spectrum of activities involving GMOs and products thereof including sale, storage, exportation, importation, production, manufacturing, packaging, etc. These rules are implemented by the MoEFCC, the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and State Governments. Six Competent Authorities and their composition have been notified under the Rules, 1989 .

1. Recombinant DNA Advisory Committee (RDAC)	Advisory
2. Institutional Biosafety Committee (IBSCs) 3. Review Committee on Genetic Manipulation (RCGM) 4. Genetic Engineering Appraisal Committee (GEAC)	Approval
5. State Biotechnology Coordination committee (SBCC) 6. District Level Committee (DLC)	Monitoring

Fig 5: Competent authorities notified under Rules, 1989

While the RDAC is of advisory in function, the IBSC, RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes (Figure 5). In addition to the above, Central Compliance Committees (CCCs) are set up by the RCGM to monitor the field performance of GM crops.

Rules, 1989 mandate that no person shall import, export, transport, manufacture, store, process, use or sell any GMOs, substances or cells except with the approval of GEAC. Further for permission from GEAC has to obtain for scale up pilot operation or production facilities. Deliberate or unintentional release of GMOs shall not be allowed.

GEAC also have powers to revoke approvals in case of:

a. Any new information on harmful effects of GMOs.

b. GMOs cause such damage to the environment as could not be envisaged when approval was given.

c. Non-compliance of any conditions stipulated by GEAC.

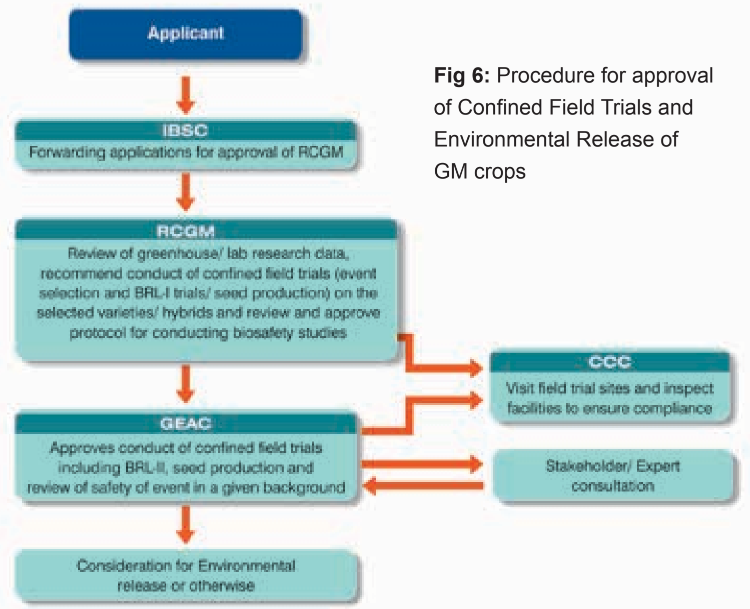


Fig 6: Procedure for approval of Confined Field Trials and Environmental Release of GM crops

GEAC has adopted Event Based Approval Mechanism (EBAM) for Bt Cotton Hybrids in 2008. As per new procedure, Bt cotton hybrids expressing approved events and developed through conventional backcrossing are exempted from conduct of detailed biosafety studies as required for new events. All such cases are referred to a Standing Committee constituted by the GEAC. The new procedure lays down specific information to be submitted to the Standing Committee for taking a final view on the performance and suitability of a particular Bt Cotton hybrid/variety for a specific zone. Requirement for seeking approval from the State Government for the conduct of Confined field trial has also been introduced by GEAC. The Figure 6 depicts the process of seeking approval of confined field trials and environmental release of GM crops.

The GEAC has the authority to supervise the implementation of terms and conditions laid down in connection with the approvals accorded by it through the SBCC/DLC/State Pollution Control Board (SPCB) or any person authorised by the GEAC. If an order is not complied with, there is provision for imposing penalties including immediate intervention by the SBCC/ DLC in orderto prevent damage to the environment, nature and health without issuing any orders at the expense of the person responsible for such damage. GEAC also has the authority to exempt an occupier handling a particular GMO from the provisions of Rules, 1989.

Supporting guidelines for GM crops

Rules, 1989 are implemented by competent authorities through a series of biosafety guidelines, that are issued for every step of the development process of GM crops (Box 1).

Box 1: Biosafety Guidelines for GM crops in India

Contained Use

- Recombinant DNA Safety Guidelines, 1990 (Updated, 2017)
- Revised Guidelines for Research in Transgenic Plants, 1998

Confined Field Trials

- Guidelines for Conduct of Confined Field Trials of Regulated GE Plants, 2008
- Standard Operating Procedures (SOPs) for CFTs of Regulated GE Plants, 2008
- Guidelines for Monitoring of Confined Field Trials of Regulated GE Plants, 2008

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

Environmental Safety Assessment

- Guidelines for Environmental Risk Assessment (ERA) of GE Plants, 2016
- Risk Analysis Framework, 2016
- ERA of GE Plants: A Guide for Stakeholders, 2016

Section 4: Confined field trials

GM crops are permitted to be grown only after they have passed safety assessments and are not likely to pose risks for human health and environment. The data requirements for safety assessment are extremely rigorous for GM crops and are defined by regulatory authorities. Developers of GM crops (both public and private sector) test their products according to regulatory requirements which include detailed documentation of testing. Regulatory authorities undertake thorough analysis of the data and the protocols used to ensure the validity of the results. Additional information and additional testing may be asked by the regulatory agencies, if the data is not sufficient. During the course of development, researchers/product developers review safety of the products at each step and may stop further development if there are doubts. The GM crops and foods that are currently on the international market have all passed safety assessments conducted by national authorities.

As part of safety assessment, GM crops are required to go through field-testing so that they can be evaluated for their biosafety as well as agronomic performance before being released for use by the farmers. As GM crops may contain one or several additional genes than the conventionally bred crops, their field-testing is carried out under conditions to ensure that the materials tested remains within the trial site; and hence, such trials are referred to as CFTs.

CFTs of GM crops are similar to field trials regularly done for conventional breeding, except that they are confined to the particular site. CFTs are conducted with the following objectives:

i. Test the GM plants under real field conditions
ii. Test the efficacy of the inserted genes/introduced trait in the local environment under different agro climatic conditions
iii. Enable selection of superior lines for development
iv. Generate safety data needed for subsequent risk assessment and approval

v. Breed biotech trait into local varieties

vi. Scale-up of production material, prior to commercial approval

In a confined field trial, biological and physical confinement measures are used to restrict GM plant material to a specific area of the environment and these research trials are thus considered globally as extensions of contained experimentation. CFTs are performed under stringent terms and conditions that confine the experimental material. It has been well established globally that confined field trials can be performed safely and routinely by focusing on material and genetic confinement measures.

Guiding Principles to confine a field trial

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

- **Material Confinement** ensure the effective confinement of the experimental genetically engineered material so that it is not eaten by humans or livestock.
- **Genetic Confinement** ensure reproductive isolation to prevent plants from pollinating compatible species and producing seed that escapes from the trial site.
- **Post Harvest Land Use Restrictions** prevent the persistence of the genetically engineered material in the environment by ensuring that the genetically engineered materials and any volunteers arising from the trial are completely destroyed.

While general principles and standard terms and conditions remain the same for all CFTs, specific conditions to be laid for each CFT vary according to the crop, the introduced trait and the locations/ environment.

All the plant material from a CFT that is not retained for research purpose is destroyed by supervised incineration (Figure 7) after completion of the trial in the presence of officials from relevant state department of agriculture.

Fig 7: Destruction/Incineration

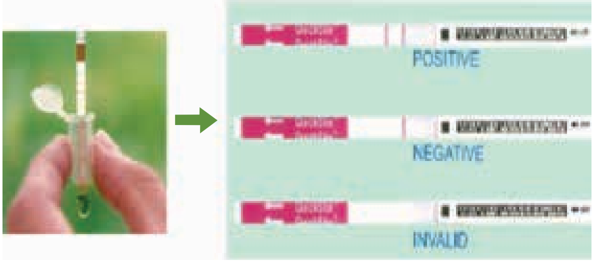
Section 5: Detection of GM crops

Generally, GM crops are indistinguishable from the non-GM crops to the naked eye. It is even more difficult to identify the novel genes in the products derived from these crops. Therefore, it is extremely important to have the detection methods for ensuring the quality concerns of GM crops and ascertaining the efficacy of products by users i.e. farmers, seed industry, regulatory authorities etc.

Testing methods for GM crops look for the genes (DNA) engineered into the particular crop or the proteins produced in the crop by the introduced DNA. Each method is appropriate under certain conditions and it is important to be aware of the same when selecting an appropriate GM testing method. In line with the above, analytical methods to detect (qualitative or yes/no answers) and quantify (percentage content) in a GM crop.

The commonly used test methods are as follows:

i) **Strip test:** Unskilled personnel in the actual field can carry out these tests. Typically, a sample for testing is crushed and mixed with water. The strip is dipped into this mixture and the result monitored as the colour of the strip changes indicating whether or not the GMO variety is present.



ii) **Enzyme-linked immune sorbent assay (ELISA) based tests:** This test uses antibodies (polyclonal or mammalian) raised against a specific protein encoded by transgene. These antibodies are colour coated to enable them to be easily detected and quantified. This test is conducted in a laboratory.

iii) **DNA based tests:** This test detects the specific transgene in the GM crop or specific elements associated with the transgene by targeting and multiplying/amplifying the same through polymerase chain reaction (PCR) technique. The amplified DNA is then visualized using the gel electrophoresis technique. A positive result is indicated by a band on the gel and a negative result by no band. This test can be conducted only in laboratories.

In India, several public and private sector organizations have capabilities for detection of LMOs. There are also companies supplying various types of test kits. Four laboratories, strengthened under Phase II Capacity Building Project on Biosafety have been designated as National Referral Laboratories to detect for the presence or absence of GM crops/GMOs under the Seeds Act, 196

The laboratories strengthened for detection of GM crops /GMOs include:

1. DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Department of Agriculture, Government of Andhra Pradesh, Guntur, Andhra Pradesh
2. ICAR-National Bureau of Plant Genetic Resources (NBPGR), New Delhi
3. Export Inspection Agency (EIA), Kochi Laboratory, Kochi, Kerala
4. Punjab Biotechnology Incubator (PBTI) Mohali, Punjab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