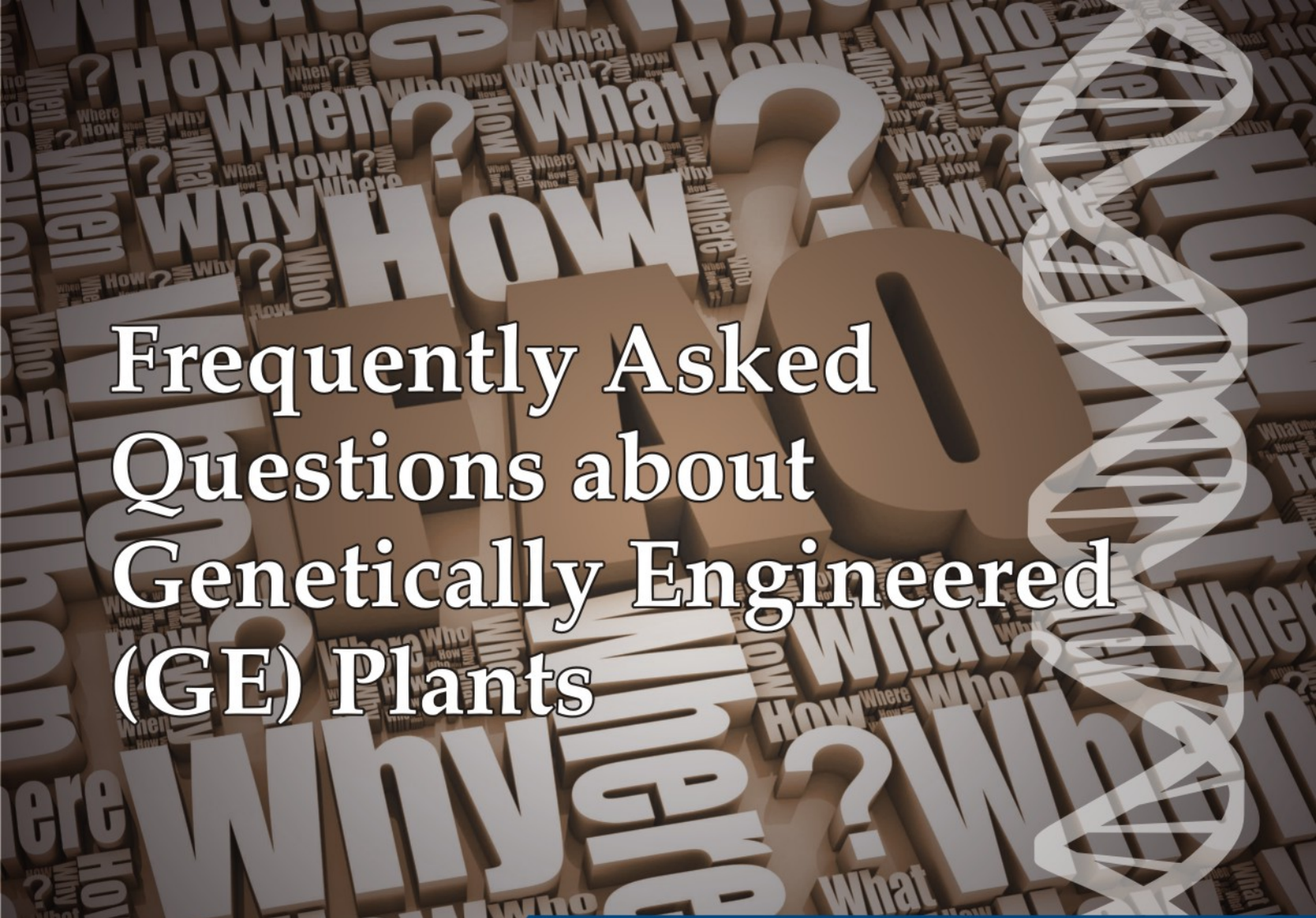

Frequently Asked Questions about Genetically Engineered (GE) Plants

Phase-II Capacity Building Project on Biosafety

सत्यमेव जयते

UNEP

gef

Nature Protects if She is Protected

Ministry of Environment, Forest and Climate Change

Government of India

In association with

BCIL

Biotech Consortium India Limited

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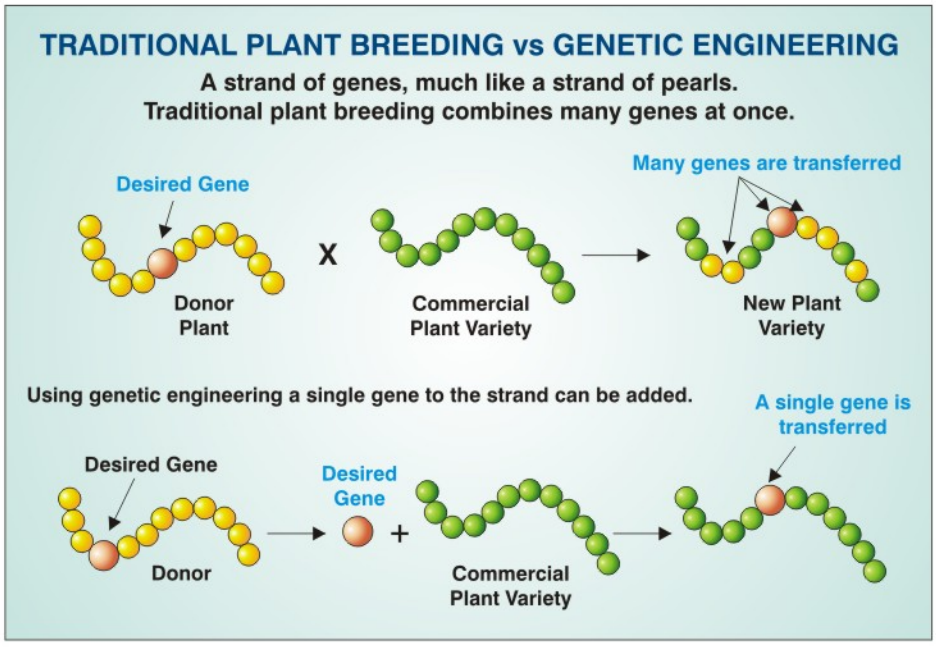
1 What are Genetically Engineered (GE) Plants ?

Genetically engineered (GE) plants are plants, in which the basic genetic material (DNA) has been altered using genetic engineering techniques. In most cases the aim is to introduce a new trait to the plant. GE plants are also referred as genetically modified (GM) crops, transgenic plants or biotech crops.

2 How are GE Plants different from those developed using traditional plant breeding techniques ?

- Traditional breeding has been long used in agriculture to obtain desirable characteristics of plants. This process may involve random transfer of thousand of genes and take many years to produce the desired characteristics.
- Genetic engineering techniques allow the introduction of one or more of the desired genes to be introduced precisely into the host organism for the development of desired features.
- Genetic engineering is similar to conventional breeding in terms of objective of generating more useful and productive crop varieties containing new combination of genes.
- Genetic engineering enables introduction of useful genes not just from within the plant species or from closely related plants, but from a wide range of other organisms.



DNA and Gene

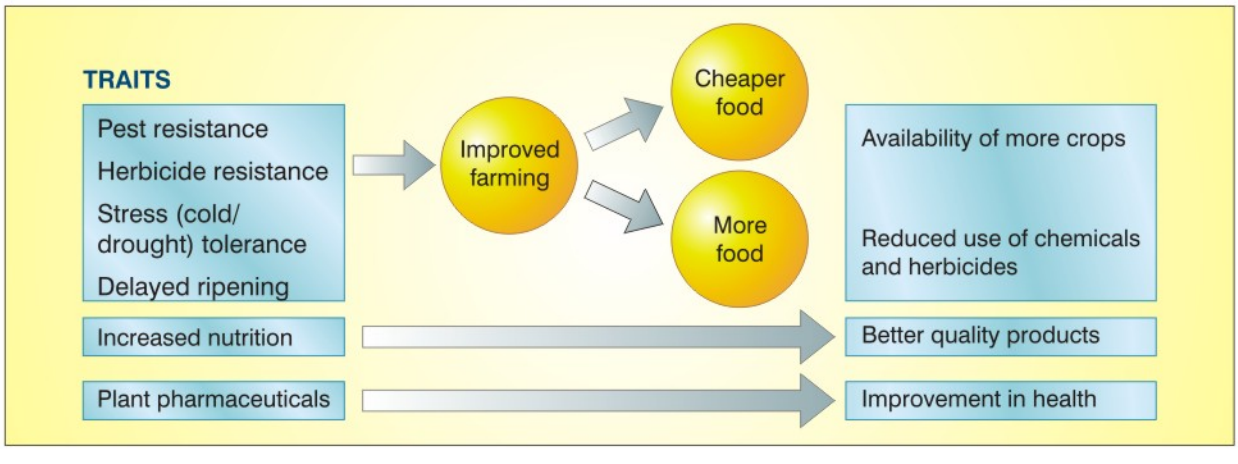
- Deoxyribonucleic acid, more commonly known as DNA, is a complex molecule that contains all of the information necessary to build and maintain an organism. All living organisms have DNA within their cells.
- A gene is a sequence of DNA that contains information that determines a particular characteristic/trait.
- Genes are units of inheritance that are passed from one generation to the next.
- All organisms have varying number of genes; for instance, the human has an estimated 60-100,000 genes, most plants have about 20,000, a nematode (a microscopic creature) has about 18,000; and the single celled *Escherichia coli* bacterium just over 4,000.
- The genetic differences among different species as well as organisms within a species lie in the difference in number and sequence of these genes in the DNA/genome.

3 How is the genetic modification possible ?

- The genetic code is universal i.e. the DNA of all organisms is made up of the same building blocks and is encoded in exactly the same way.
- A copy of DNA sequence (or gene) encoding a particular characteristics can be therefore transferred into the cell of a different organism.
- Once the gene is incorporated into the genome of a plant recipient, the resulting plant is considered to be genetically modified/engineered and the new characteristics coded by that gene are inherited by subsequent generations.

4 Why make GE Plants ?

- For thousands of years, farmers have relied on selective breeding and cross-fertilization to impart desirable traits in plants such as higher yields and resistance to pests. Through trial and error, plant varieties have been developed with altered and stable genetic traits.
- Farmers regularly need new technologies and guidance on management practices not only to increase productivity, but also to deal with abiotic and biotic stresses such as drought, salinity, diseases etc.
- As characteristics of interest do not always exists in related species, GE plants are developed to bring together useful genes from a wide range of living sources for development of superior plant varieties.
- GE plants have been developed to incorporate various traits such as insect/pest resistance, herbicide tolerance, disease resistance, altered nutritional profile, enhanced storage life etc. for benefits such as
  - ❖ 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 lead to preservation of natural resources like soil and water due to decreased tillage
  - ❖ improved weed control due to use of herbicide resistant GE plants



5 What are the steps involved in development of a GE Plant ?

The development of a GE plant involves the following :

- **Identification of a gene:** The first step is the identification of a gene(s) responsible for a desired trait in an organism (plant, animal or microorganism) followed by isolation and copying the gene of interest by use of molecular biology techniques.
- **Designing genes for insertion:** Once isolated and cloned, the gene of interest has to be modified with additional components (referred to as gene construct) before it can be effectively inserted into the host plant. These may include addition of a promoter and termination sequences to signal the initiation and completion of the sequence of gene of interest and marker gene for identification of GE cells/tissues during experimental process.
- **Transformation:** The gene construct is then transferred to the host plant through process of transformation using a Gene Gun method or the Agrobacterium method. Transformation is a heritable change in a cell or organism brought about by the uptake and establishment of introduced gene in the host plant.
- **Selection:** Following the gene insertion process, plant tissues are transferred to a selective medium (such as containing an antibiotic or herbicide), depending on the type of selectable marker used. Only plants expressing the selectable marker gene will survive indicating that they possess the transgene of interest. The whole plants are generated using tissue culture methods for further evaluation in laboratories and green houses. The evaluation includes activity of the introduced genes, stable inheritance of the genes and any unintended effects on plant growth, yield quality etc.
- **Field Trials and Safety Assessment:** The next step in the process is multi-location and multi-year evaluation trials in greenhouse and field environment to test the effects of the transgene and its overall performance. This phase also includes evaluation of environmental effects and food safety.
- All data/ information generated through above experimental trials and studies are evaluated by regulatory authorities before granting permission for environmental release or commercialization.

6 Which plants have been subjected to genetic engineering ?

- Plants being subjected for 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.
- Some of the commercially cultivated GE plants in various countries are as follows:

Bt Cotton

- Contains a built-in insecticidal protein from naturally occurring soil microorganisms *Bacillus thuringiensis* (Bt) that gives protection to cotton from budworms and bollworms.
- Reduces or eliminates the need for additional insecticide applications for these pests as Bt is effective only to target pests but does not harm humans, animals, fish, birds and beneficial insects.

Herbicide tolerant Soybean

- Contains a gene that provides resistance to selective herbicides.
- Provides better weed control, thereby improves farm efficiency by optimizing productivity and saving time for farmers.

Virus resistant Papaya

- Contains a viral gene that encodes for the coat protein of papaya ringspot virus (PRSV).
- Provides the papaya plant with built-in protection against PRSV.

GE Maize

- Has been developed incorporating both insect resistant and herbicide tolerant genes.
- Drought tolerant maize containing genes to maintain normal physiological performance during stress events has also been approved for commercial cultivation.

Hybrid Canola

- Contains transgenes for a hybrid breeding system through development of male sterility and fertility restorer lines.
- Helps in production of hybrids for increasing yields.

Several new GE plants with variety of traits are under research and development. Some of the examples are:

Golden Rice

- Beta-carotene gene incorporated in rice that lead to development of rice with enhanced level of beta-carotene.
- Provides better vitamin A level, thereby reducing its deficiency.

Nitrogen use efficient crops

- Genes have been introduced to develop crop plants such as rice, wheat and canola that absorb and use nitrogen more efficiently.
- Help in achieving increase in yields while significantly reducing fertilizers etc.

7 What are the concerns regarding safety of GE Plants ?

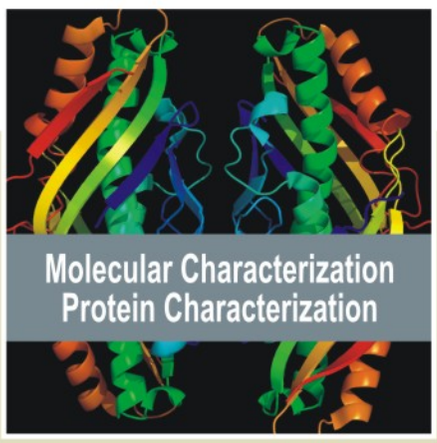
- As with any new emerging technologies, safety concerns have been expressed with the use of genetic engineering.
- The use of GE organisms and products has been accepted more readily in healthcare, as these are directly beneficial for consumers (e.g. vaccines, medicines with improved treatment potential or increased safety).
- Concerns have been expressed about GE plants by some groups since their introduction in the mid-1990s, primarily because of the perception that modern biotechnology tools such as genetic engineering lead to creation of new species.
- Safety concerns associated with the use of GE plants broadly relate to risk to human and animal health, and environment. These differ greatly depending on gene-crop combination, and may include:
  - ❖ Potential risk of introducing toxins, allergens and other anti-nutrition factors in foods.
  - ❖ Potential likelihood of transgenes escaping from cultivated crops into wild relatives.
  - ❖ Changes in weediness potential.
  - ❖ Interaction with non-target organisms.
  - ❖ Resistance/tolerance of target organisms.

8 Are GE Plants assessed differently from conventional plant varieties ?

- Traditionally the plant varieties are considered safe based on their history of safe use.
- In practice, very few of the foods we eat today have been subject to any toxicological studies and yet they are generally accepted as safe.
- Whenever new plant varieties are developed using the conventional breeding methods, some of the characteristics may be altered either in a positive or negative way. However, they are not generally subjected to any safety assessment process.
- In contrast, all GE plants undergo rigorous evaluation to ensure safety to human health and the environment.

9 How is the safety of a GE Plant evaluated ?

- Evaluating the safety of a GE plant is a comprehensive process that involves several steps.
- Systematic safety assessment methodologies are in place that have been agreed upon years of consultations under the aegis of international organizations and agreements viz. FAO, WHO, Codex Alimentarius, OECD and Cartagena Protocol on Biosafety.
- The potential changes introduced using genetic engineering are assessed using comparative risk assessment approach. The underline assumption of this comparative approach is that traditionally cultivated crop has a history of safe use and thus serves as the comparator. As a consequence, safety assessment process gives conclusion on whether or not the GE plant is as safe as its conventional non-GE counterpart.
- Safety assessment studies required for commercial release of a GE plant comprise of food and feed safety assessment and the environmental risk assessment coupled with information through the molecular characterization of the GE plant and characterization of the expressed, transgenic proteins.
- Impact on human health is studied by analyzing the modified organism for the risks of toxicity, allergenicity, nutritional analysis etc. as relevant to the particular situation of targeted genetic modification. The toxicity and allergenicity assessment takes into account the chemical nature and functions of the newly expressed substance, the concentration of the substance in the edible plant parts and likely dietary exposure. Appropriate oral toxicity studies in laboratory animals are also carried out on a case by case basis. For allergenicity, data is generated on amino acid homology for expressed proteins with known allergens from bioinformatics data base, heat stability, pepsin digestibility etc in an integrated step-wise manner. Nutritional equivalence is established through detailed compositional analysis by comparing concentration of key components in GE plants with a conventional counterpart that is grown and harvested under the same agro-climate and growing conditions. Livestock feeding studies may also be carried out in specific cases.
- Environmental risk assessment of GE plants is undertaken on a case to case basis and there is no single method or model to follow in view of diverse biological properties of crops. Familiarity i.e. knowledge and experience of unmodified plant is basis for comparative risk assessment of a GE plant. Baseline information as documented in biology documents is used as basis for this comparison. Potential changes that are compared include weediness/ invasiveness, gene flow pattern of the introduced trait, impact on non-target beneficial organisms etc.



10 Are GE Plants safe ?

- Different GE plants include different genes inserted in different ways. Accordingly, GE plants containing specific genes and their safety is assessed on a case-by-case basis.
- It is not possible to make general statements on the safety of all GE plants being developed.
- GE plants 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 GE plants and foods that are currently on the international market have all passed safety assessments conducted by national authorities.
- These different assessments in general follow the same basic principles, including an assessment of environmental and human health safety.

11 Who performs the safety assessment ?

- The data requirements for safety assessment are extremely rigorous for GE plants and are defined by regulatory authorities.
- Developers of GE plants (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.
- Such reviews are standard scientific methods of evaluation used by regulators around the world to evaluate the health and safety of a variety of products including food and drugs. Methods used are based on international expert consultations under the aegis of organizations such as WHO, FAO, Codex, OECD and other international agreements such as Cartagena Protocol on Biosafety.

12 Why do GE Plants contain antibiotic resistance gene ? Do these gene affect human health ?

- In the process of genetic modification, antibiotic resistance genes are used as markers for identification of cells into which the desired gene has been successfully introduced.
- Concerns have been expressed about the possibility of transferring these genes from GE plants/foods to bacteria that is normally present in the human gut and resulting in the development of antibiotic resistance in these bacteria.
- There have been numerous scientific studies on this issue and it has been concluded that the likelihood of antibiotic resistance gene moving from GE plants to any other organisms is extremely remote (< 10-14 to 10-27) or virtually zero.

13 Has there been any GE Plant withheld from entering the market as a result of failing the safety assessment ?

- 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.
- For example, a trial was conducted in 1996 to improve the nutritional content of soya bean, which has low content of methionine - an essential amino acid. It involved inserting a gene from Brazil nut to achieve high methionine content. Since Brazil nuts are allergenic to some people, the trial included screening for this side effect and it was found that the soya bean contained an allergen from Brazil nuts.
- The development of this soya bean was then stopped, thus this soya bean was never commercialized. This example illustrated the effectiveness of the safety assessment system in protecting public health.

14 Are there long-term health effect of foods from GE Plants ?

- The only difference between the GE and Non GE foods is the inserted gene product- a protein.
- The safety of the consumption of this protein is established based on its biological properties and tests of digestibility, acute toxicity, allergenicity.
- Once this is done and safety established then the compositional equivalence confirms that the GE crop/ food is similar to corresponding Non GE which has been used / consumed traditionally for generations and hence no long term effects are expected to be seen based on this history of safe human use.

15 Are foods from GE Plants less nutritious than comparable foods ?

- Detailed compositional analysis is an essential part of the safety evaluation process.
- Prior to approval, it is necessary to demonstrate that GE plants presently being cultivated are as nutritious as foods from comparable traditionally bred plants.

16 Are GM Seeds Sterile ? Why do farmers have to purchase seeds of GE Plants every year ?

- Seeds of GE plants are not sterile. Terminator seed technology or genetic use restriction technology (GURT) is banned in the country. Every GE plant developed is first tested for absence of terminator / GURT technology.
- Whether the farmers have to purchase seeds every year depends on whether he is growing variety or hybrids. As in the conventional seed production, farmers can save seeds in case of varieties and in case of hybrids they will have to purchase it every year. The same practice has to be followed in GE plants.
- The hybrids are produced by crossing two different varieties of the same crop plant and thereby incorporate certain desirable characteristics of both plants.
- The reason why farmers have to purchase seeds in case of hybrid cultivation, is because only F1 (First Generation) seeds are recommended as there is a possibility of segregation of the parental traits during the F2 seeds thereby reducing the optimum productivity. This is applicable for both non-GE and GE hybrids.

17 How long have GE plants been cultivated and are in the market?

- The application of modern biotechnology in agriculture was started in the 90s.
- The first GE plant FlavrSavrTM tomato, was approved in the United States in 1994.
- As per the available reports, 16 GE plants have been cultivated in 28 countries in 2014.
- As on 2014, a total of 3,083 regulatory approvals involving 27 GE plants and 357 GE events have been issued by competent authorities in 65 countries, of which 1,458 are for food use (direct use or processing), 958 are for feed use (direct use or processing) and 667 are for planting or release into the environment.

Status of approval for cultivation of GE plants in various countries in 2014

S.N.	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, Argentina, India, Columbia. Burkino Faso, Sudan, Pakistan, Brazil, Myanmar, Paraguay, Costa Rica
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

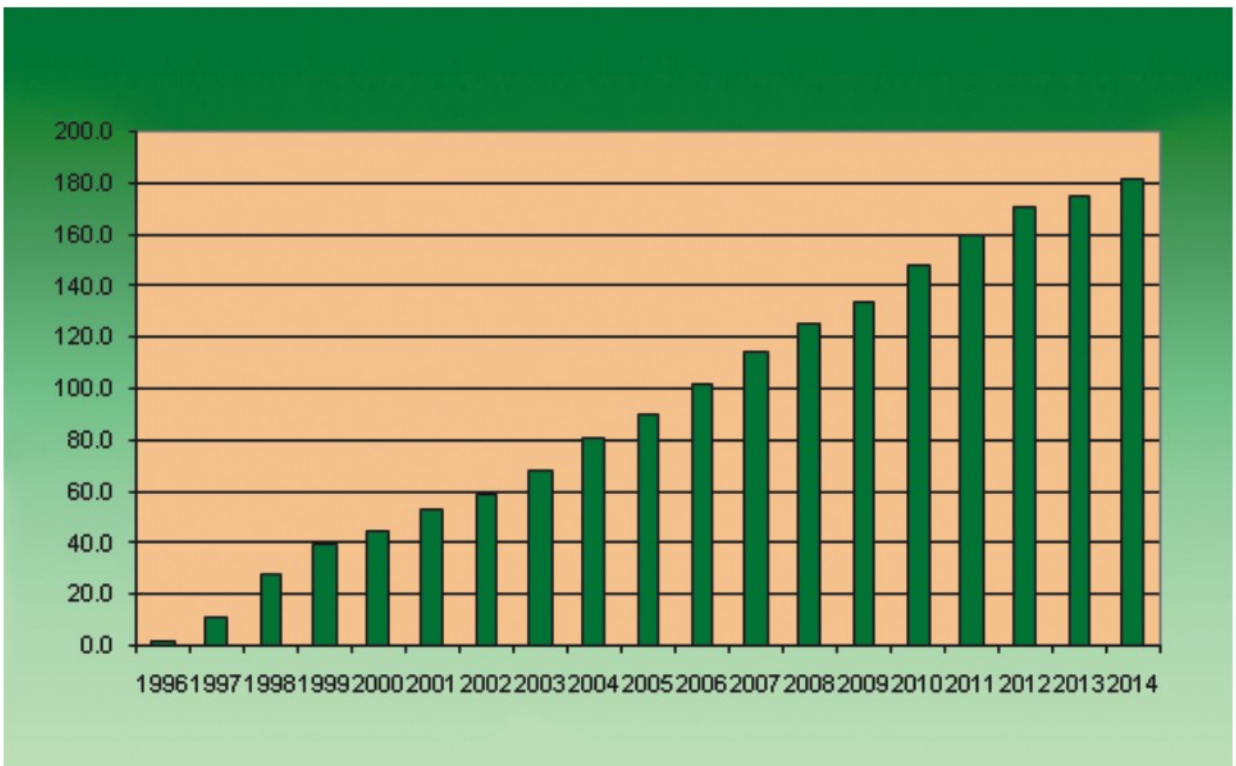
Source: **ISAAA** Global Status of Commercialized Biotech/GM crops, 2014.

- In addition, Vietnam approved the commercial cultivation of stacked Bt/Ht maize in 2015, expected to be planted in the near future. Brazil has recently approved GM Eucalyptus, an important pulp and paper producing tree.

18 How widely used are GE Plants ?

- The area under cultivation of GE plants has increased from 1.7 million hectares in 1996 to 181.5 million hectares in 2014 grown by over 18 million farmers globally.
- While 28 countries planted commercialized biotech crops in 2014, an additional 31 countries have granted regulatory approvals for GE plants for import as food and feed use.

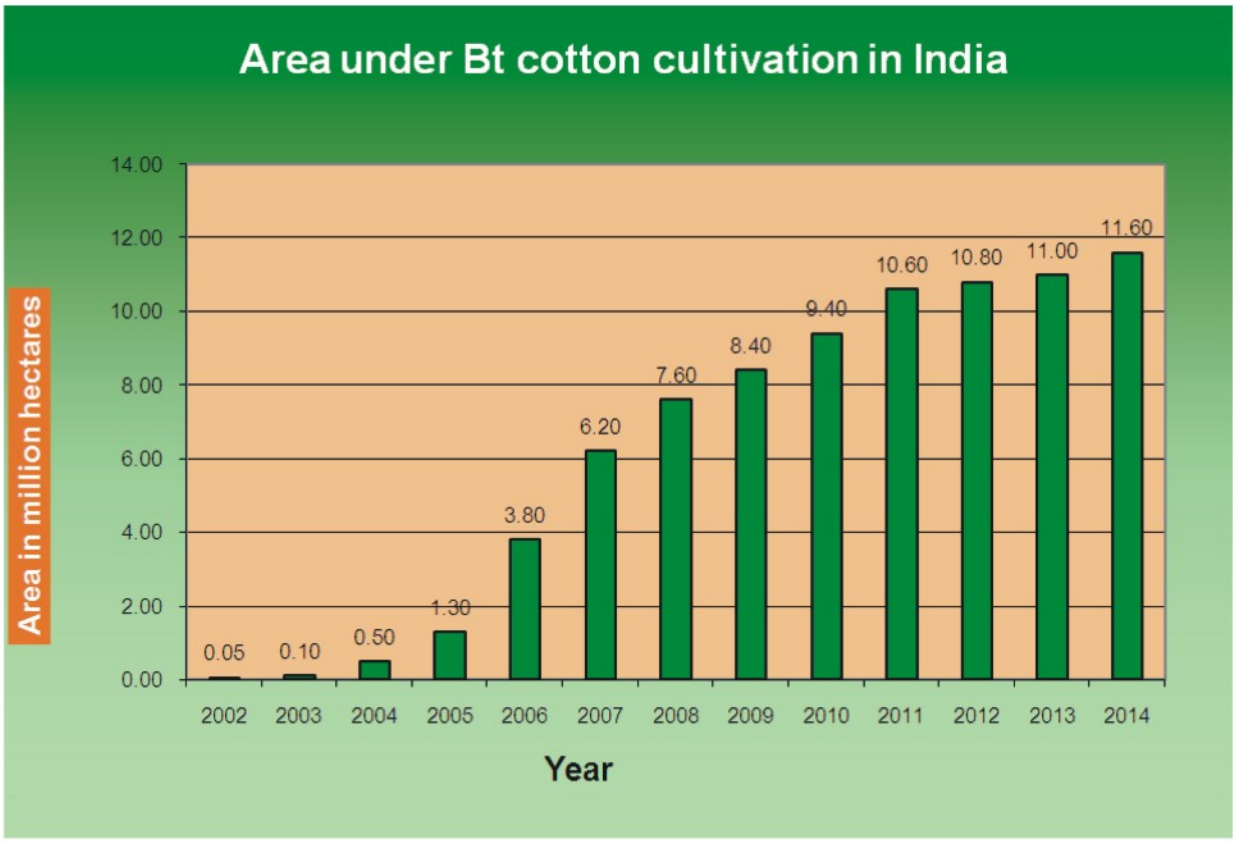
Global area of transgenic crops from 1996 to 2014 (million hectares)



Source: International Service for the Acquisition of Agri-biotech Applications (http://www.isaaa.org)

19 How many GE Plants are approved and cultivated in India ?

- To date, Bt cotton is the only GE plant approved for commercial cultivation in India.
- The total area under Bt cotton has increased from 0.05 million hectares in 2002 to 11.6 million hectares in 2014.
- As of now, Bt cotton is cultivated in more than 90% of the area under cotton: in terms of area under cultivation under GE plants, India is fifth in the world after USA, Brazil, Argentina and Canada.



20 What are the GE Plants under research and development in India ?

- Several public and private sector institutions are involved in the research and development of GE plants in India.
- More than 20 plants with varying traits such as hybrid seed production, insect resistance, herbicide tolerance, abiotic stress tolerance, nutritional enhancement etc. are under various stages of field trials.

An indicative list of GE plants under research and development/ field trials in India

S.N.	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

Genetic Modification is a technique that changes the genetic makeup of cells, including alteration of genetic material and allow genes to move across species. It produces new combinations of genes and traits that do not occur in nature. Plants that have been altered in this way are called genetically engineered (GE) plants or transgenic plants. Being a novel technology, safety concerns related to impact on human health and environment have been expressed about GE plants.

In India, Bt cotton is the only GE crop under commercial cultivation since 2002. In addition several GE Crops are at various stages of research and development both in the Public and Private sector.

This brochure aims to provide some basic information about genetic engineering, GE plant and its development, safety assessment, and current status of GE plants with a view to enhance awareness on the technology and facilitate information sharing among various stakeholders.

This brochure is a part of **Biosafety Resource Kit** prepared under the Phase II Capacity Building Project on Biosafety being implemented by the Ministry of Environment, Forest and Climate Change.

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