Plant Archives Vol. 25, No. 2, 2025 pp. 563-578 e-ISSN:2581-6063 (online), ISSN:0972-5210

Plant Archives

Journal homepage: http://www.plantarchives.org

DOI Url : https://doi.org/10.51470/PLANTARCHIVES.2025.v25.no.2.077

STATUS OF TRANSGENIC RESEARCH IN INDIA WITH REFERENCE TO CROP PLANTS

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(Date of Receiving-11-06-2025; Date of Acceptance-27-08-2025)

ABSTRACT

The plants produced by the insertion of specific segments of foreign nucleic acid/gene sequence into its genome using transformation methods are known as transgenic plants. The inserted gene, also known as transgene, may come from an unrelated plant, bacteria, virus, fungus, or an animal species. Transgenic production will allow us to feed the growing population and to produce more desirable products. This process provides advantages like improving shelf life, higher yield, improved quality, pest resistance, tolerant to heat, cold and drought resistance, against a variety of biotic and abiotic stresses. Transgenic crops enhance agricultural productivity, reduce environmental impact, enhance nutritional value, reduce the use of chemical pesticides. Transgenic plants can also be produced in such a way that they express foreign proteins with industrial and pharmaceutical value. To date, nearly 525 different transgenic events in 32 crops have been approved for cultivation in different parts of the world. An example of a transgenic crop is Bt cotton, which is widely grown in several countries, including India. Globally, 82% of the total crop area for soybeans, 68% for cotton, 30% for maize and 25% for oilseed rape were planted with GM varieties in 2014. The future of GM crops remains a vital debate, as its applications have several advantages and disadvantages. Widespread adoption of transgenic crops carrying foreign genes faces roadblocks due to concerns of potential toxicity and allergenicity to human beings, potential environmental risks, such as chances of gene flow, adverse effects on non-target organisms, evolution of resistance in weeds and insects etc. Safety assessment, transgenic cultivars with significant improvement in yield, quality, or adaptability are important for approval and commercial release. India must continue its research on GM crop and its deregulation along with building basic infrastructure facilities and preparing stringent biosafety and marketing guidelines.

***Keyw ords*: Transgenic, Genetically Modified Varieties**

Introduction

Importance of Transgenics

The food demand of the world population is increasing for yield, quality, and adaptability of crop cultivars are becoming more and more urgent (Barrett, 2021). The limited genetic variation within nature or mutagenized populations of sexually compatible species, conventional approaches to crop improvement (systematic breeding, crossing breeding, and heterosis utilization) are laborious and time-consuming. Transgenic technology overcomes hybridization barriers and utilizes the desirable genes from genetically distant species, to realize molecular design breeding (Raymond Park *et al.*, 2011; Kamthan *et al.*, 2016). It provides a revolutionary impact on crop improvement as a second Green Revolution, greatly improving the yield, quality, and adaptability of crops and making an important contribution to ensuring food security (Eckardt *et al.*, 2009; Farre *et al.*, 2010; Kamthan *et al.*, 2016). The "Flavr Savr" tomato was the first transgenic plant developed by Celgene. These transgenic tomatoes are more resistant to rotting due to an antisense gene that interferes with Beta polygalacturonase and regulate the ripening of the tomatoes. It paved the way for developing other transgenic plants such as Bt cotton, Bt brinjal, and Golden rice. A GM soybean variety that produces oil with a healthier fatty acid composition, a GM non-browning apple, and GM potatoes with lower acrylamide content after frying have recently received approvals in some countries, and are beginning to enter the market. Achieving a balance between the advantages of transgenics and environmental risks is imperative for ensuring sustainable agriculture and food security (Lucht, 2015 and Ngongolo and Mmbando, 2025).

Definition of Transgenics

The plants produced by the insertion of specific segments of foreign nucleic acid/gene sequence into its genome using transformation methods (such as Agrobacterium-mediated transformation or direct gene transfer) are known as transgenic plants (Griffiths *et al.*, 2005). The inserted gene, also known as transgene, may come from an unrelated plant, bacteria, virus, fungus, or an animal species. The word "Transgenic" stands for any external genetic feature artificially introduced into the genome of another organism to get desired features. This gene extracted with the help of a restriction endonuclease enzyme (molecular scissors) is inserted into the target genomes by methods such as Particle Gun or gene gun or biolistic, PEG (polyethylene glycol mediated transformation), Electroporation, Agrobacterium-mediated gene transfer. They are also known as genetically modified organisms (GMOs) as the process involves insertion of one or more genes from a different species into the plant's genome to confer certain advantageous traits that are not naturally present in the species. Genetically Modified Organism (GMO) and transgenic organism are two terms that are used interchangeably. Both have altered genomes, but a transgenic organism is a GMO which contains a DNA sequence or a gene from a different species. GMO is an animal, plant, or microbe who's DNA has been altered using genetic engineering techniques (Raymond Park *et al.*, 2011; Kamthan *et al.*, 2016 and Georges and Ray, 2017). GMO crops have altered DNA through genetic engineering, either by modifying native genes or introducing foreign ones. Transgenic crops, a subset of GMOs, contain genes from other species like bacteria or animals. Thus, all transgenic organisms are GMOs, but not all GMOs are transgenic.

Methods of transgenics production

It Includes introduction of the gene (s) coding for certain traits into a plant cell, and then regeneration of a plant through tissue culture. There are three ways to modify genes in the cells. The widely used technique for delivering exogenous DNA is microparticle bombardment. The other ways to deliver DNA into plant cells, including electroporation into protoplasts, microinjection, chloroplast transformation, silicon-carbide slivers, mesoporous silica nanoparticles (Barampuram and zhang,2011). However, particle bombardment remains more effective at transferring large DNA fragments – even whole chromosomes – simultaneously (Schmidt *et al.*,2008). The use of Agrobacterium tumefaciens opened a new era for inserting exogenous genes into plant cells. The bacteria possess a tumor-inducing plasmid ("Ti-plasmid"), which enable them to accomplish gene-insertion (Manish Shukla *et al.*, 2018 and Jhansi and Usha, 2013).

Types of Transgenic Crops

They include insect-resistant (Bt cotton), herbicide-tolerant crops (ex: GM soybean), crops modified to resist viral, bacterial, or fungal infections (ex: virus-resistant papaya), nutritionally enhanced crops, enriched crops with vitamins or minerals (ex:., Golden Rice with provitamin A),stress-tolerant crops (engineered to withstand environmental stresses such as drought or salinity (ex: drought-tolerant maize), delayed ripening crops (extended shelf life (ex: Tomato).) and crops engineered to produce toxins (ex: Bt cotton) that protect against insect pests.

Status of Transgenic crops at global level

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) indicated that more than 18 million farmers in 29 countries, including 19 developing nations, planted GMO crops over 190 million hectares in 2019(Genetic Literacy Project, Policy & Performance Review, 2024).

Argentina, Australia, Bangladesh, Bolivia, Brazil, Canada, Chile, China, Colombia, Costa Rica, Czech Republic, Honduras, India (Bt cotton only), Malawi, Mexico, Myanmar, Nigeria, Pakistan, Paraguay, Philippines, Portugal, South Africa, Slovakia, Spain, Sudan, Swaziland, United States, Uruguay, Vietnam, and Zambia are the developed countries growing GMO crops. Developing countries are allowing cultivation of GMOs on a case-by-case basis. These countries include Kenya (, Zimbabwe (corn), India (Bt cotton), Burkina-Faso (Bt cotton), Swaziland (Bt cotton), Zambia (all crops) and Cuba (corn and soybean). The five major GM crops planted at more than one million hectares are soybeans (95.9Mha), maize (58.9Mha), cotton (24.9Mha), canola (10.1mha), and alfalfa 1.2Mha) (ISAAA, 2020). The Usa, Argentina and Canada are the major producers and exporters of GM crops (James, 2010) while Argentina, Brazil, China and India are the developing countries producing transgenics (James, 2015)

Twenty-six countries had total or partial bans on GMOs *viz;* Switzerland, Australia, Austria, China, India, France, Germany, Hungary, Luxembourg, Greece, Bulgaria, Poland, Italy, Mexico and Russia," and significant restrictions on GMOs exist in about 60 other countries (James,2010,2012 and 2015).

The Algeria and Madagascar in Africa; Turkey, Kyrgyzstan, Bhutan, and Saudi Arabia in Asia; Belize, Peru, Ecuador, and Venezuela in South and Central America and 28 countries in Europe banned GMO' crops. Russia is the most populous country to ban both the cultivation and importation of GMO crops. In 2014, Russia banned the importation of GM crops and officially banned their cultivation, with an exception allowed for scientific research. However, in 2020, Russia reversed the importation ban on soy and has funded research on the development of gene-edited foods within its borders. Although many EU countries do not grow GMOs, Europe is one of the world's biggest consumers of them. More than 30 million tons of biotech corn and soy for livestock feed are imported each year, making Europe the largest regional consumer of GMOs in the world. More than 30 countries have granted approval for the cultivation of genetically modified (GM) crops in 2024. This indicates a significant growth in utilizing biotechnology as a sustainable tool to address global challenges such as food security and climate change. To date, 18 transgenic events with modified lipid content from three oilseed crops, viz., Argentine canola (4 events), safflower (2 events) and soybean (12 events), have been commercialised (ISAAA database 2019)

The first transgenic plants were developed about four decades ago with traits like antibiotic and insect resistances (Bevan *et al.,* 1983; Fraley *et al.,* 1983; Herrera-Estrella *et al.,* 1983; Murai *et al.,* 1983). The first transgenic tomato variety with delayed maturation for commercial release was approved by the food and drug administration (FDA) after stringent scientific scrutiny and credible safety assessment in 1994 (Klee, 1993; Parrott *et al.,* 2010; Giraldo *et al.,* 2019). Transgenic crops, like inset resistant cotton and maize, herbicide-resistant soybean and canola, have received marketing approval one after another (Padgette *et al.,* 1995; Schuler *et al.,* 1998; Bates *et al.,* 2005). Thereafter, transgenic technology has increased the pace of crop improvement to meet the requirements of biotic and abiotic resistance, higher yield, and nutritional value (Raymond Park *et al.,* 2011). The cry genes from soil bacteria *Bacillus thuringiensis* (Bt) are amongst the few highly exploited genes for developing insect-resistant transgenic crops. The Cry protein imparts insecticidal activities to B. thuringiensis. These plants are genetically engineered to possess endotoxin, which prevents the action of various pests that belong to the order: Lepidoptera, Coleoptera, Hymenoptera, Diptera, and Nematoda A few examples of transgenic plants are Bt cotton, Bt corn, Bt potato, and Bt tobacco. Bt maize: Another common transgenic crop is Bt maize (or corn), which like Bt cotton, contains a gene from the Bacillus thuringiensis bacterium. This allows the maize to produce a protein that is toxic to certain types of pests, notably the European corn borer. Canola (*Brassica napus*) is a high-yield oil crop Genetic modification by introducing desaturase genes and desaturase-related genes is an effective approach to reduce the high proportion of saturated fatty acids. (Napier *et al.,* 2019). Although these genes are present in the genome of canola itself (Xue *et al.,* 2018), all the nine events approved for commercial release (ISAAA, 2022) have been transformed by stacked exogenous genes from mold, algae, fungus, and yeast (Knutzon *et al.,* 1998; Napier *et al.,* 2019; Kinney *et al.,* 2022).

The International Service for the Acquisition of Agri-Biotech Applications (ISAAA, 2022) indicated the commercialized acreage of transgenic crops has increased to 176.85 million hectares in the world by 2021. This acreage distributes in more than 30 countries including industrial and developing countries. Profitability has been achieved by increasing yield and reducing input in pesticides, labor, and machinery (Naranjo, 2011; Raymond Park *et al.,* 2011; Smyth *et al.,* 2014). The extensive application of chemical pesticides not only increased production costs but also caused severe environmental pollution (Aktar *et al.,* 2009; Birkett and Pickett, 2014). Transgenic insect-resistant crops (cotton, maize, and soybean) have made a beneficial and eco-friendly impact on crop production (Matten and Reynolds, 2003; Gatehouse *et al.,* 2011; Blanco, 2012; Rocha-Munive *et al.,* 2018). A decrease in insecticide application, and the increase in yield and benefits in developed and developing countries have been documented (Showalter *et al.,* 2009). A meta-analysis shows that the application of insecticidal transgenic crops has decreased the use of synthetic pesticides by 41.67% and the cost of pesticides by 43.43%, increased the yield of crops by 24.85%, and benefited farmers by 68.78% (Klumper and Qaim, 2014). This analysis is confirmed by an actual survey on the application of transgenic insect-resistant cotton in China (Pray *et al.,* 2001). A global meta-analysis of the impact of transgenic crop adoption has estimated that on an average transgenic technology have increased crop yields by 22% which has led to an estimated 68% increase in farmer profits (Klumper and Qaim 2014). In 1996, glyphosate-tolerant ("Roundup Ready") soybean harbouring cp4epsps gene was commercialised as the first herbicide-tolerant transgenic crop. Most of the commercialised glyphosate-resistant crops harbour this gene (Dill *et al.,* 2008). About 70% to 90% of the globally produced GM cops are used as feed for food-producing animals. In the USA itself, with a high adoption of GM crops, more than 95% of food-producing animals consume GM feed (James, 2014). Transgenic, papaya ringspot-virus (PRSV) resistant papaya trees were introduced in Hawaii in 1998 after the papaya production was on the verge of collapse because of a devastating outbreak of PRSV infections (Gonsalves *et al.,* 2014).

The majority of the transgenic insect-resistant events are developed by heterologous expression of the insecticidal genes *Cry* (δ-endotoxin) from different strains of soil bacterium *Bacillus thuringiensis* (Ghareyazie *et al.*, 1997), except for 1 maize, 2 poplar, and 2 cotton events simultaneously transformed by vegetative insecticidal protein genes *vip3*, *CpTI*, and *API*, as well as double-stranded RNA transcript of gene *Snf7* from western corn rootworm (*Diabrotica virgifera*), respectively, for pyramiding broad resistance **(**Xie *et al.,* 1997; Hu *et al.,* 2001; Cui *et al.,* 2011; Ramaseshadri *et al.,* 2013). From these events, 59 cotton, 1 cowpea, 1 eggplant, 341 maize, 3 poplar, 30 potato, 3 rice, 6 soybean, 3 sugarcane, and 1 tomato cultivars resistant to lepidopteran (246), coleopteran (156), hemipteran (1), as well as multiple insects (36), respectively, have been developed and approved for commercial release (ISAAA, 2022). To date, nearly 525 different transgenic events in 32 crops have been approved for cultivation in different parts of the world (Krishna Kumar *et al.,* 2020).

Latest GM Crops and Traits (ISAAA, 2024)

Golden Rice

It is a form of rice developed through genetic engineering that aims at solving the problem of Vitamin A deficiency. It is a second-generation transgenic crop, and it focuses on improving the crop's nutritional content. The golden rice was created by transforming rice with two beta-carotene synthesis genes *viz*; Psy gene from daffodil and *Ctrl* gene from the soil bacterium *Erwinia uredovora* (*Chen Zhang et al.,2016). Golden rice is k*nown as *Malusog Rice* (healthy rice) in the Philippines, the vitamin A-enriched rice was approved for commercial propagation in the country in 2021. Golden rice is used as food in the United States, Canada, New Zealand, Australia, Nigeria, Kenya, and the Philippines (Ye *et al.*, 2000; Paine *et al.*, 2005; Chitchumroonchokchai *et al.*, 2017 and Napier *et al.,* 2019).

TELA maize

Four transgenic maize varieties with insect (stem-borer and fall armyworm) resistance and drought tolerance traits were approved for cultivation in Nigeria in 2024.

TR4-resistant banana

GM Cavendish banana QCAV-4 resistant to the fungal disease Fusarium wilt tropical race 4 (TR4) or Panama disease has been licensed in Australia for commercial cultivation in 2024.

Yield-enhanced eucalyptus

GM eucalyptus with volumetric wood increase, herbicide tolerance, insect resistance, and antibiotic resistance traits have been approved for cultivation in Brazil in 2024.

Glowing petunia

Designed by Light Bio for gardens and homes, Firefly Petunias glow brighter under sufficient sunlight and optimum growth conditions in 2024.

G.M. Crops in the Pipeline

Internationally recognized researchers and institutions are focusing their efforts on the development of GM products aimed at addressing global challenges in agriculture, nutrition, and sustainability (ISAAA, 2024).

The newest Rice project has developed nitrogen-efficient, water-efficient, and salt-tolerant rice with 10-15% improvement in yield, a 30% reduction in nitrogen use, and a 15% decrease in total production costs. Multi-locational trials have been conducted by the National Cereals Research Institute in Nigeria.

The National Roots Crops Research Institute in Umudike and the Donald Danforth Plant Science Centre have been developing two virus-resistant cassava varieties for East Africa, Nigeria, and other West African countries. The Nigerian VIRCA Plus product has elevated levels of iron and zinc for improved nutrition, biofortification, and disease resistance.

An international consortium, including EU research institutions and the USDA Agricultural Research Service developed Honeysweet, a plum tree resistant to the plum pox virus. The field trials showed promising results, and the developers are hoping for the final approval for commercialization in the EU in the next few years.

The University of the Philippines Los Baños developed a GM papaya resistant to the papaya ringspot virus. The field trials in 2014 and 2017 have been completed, and the preparations for further trials are in the works.

Researchers in Kenya are working on insect resistant and drought tolerant corn, Cassava Brown Streak Disease (CBSD) resistant cassava, enhanced vitamin A, zinc, and iron sorghum, and late blight resistant potato.

Indonesia has also started research on high sucrose sugarcane, Golden Rice, and Fe-Zn biofortification rice. Michigan State University (MSU) and National Research and Innovation Agency are also a step forward in conducting safety studies for both granola and diamant varieties of GM potatoes with stacked genes in 2023-2024.

Delhi University's GM mustard is slowly progressing through India's regulatory approval system. Other crops being improved in India using biotechnology are bananas, cabbage, cassava, cauliflower, chickpeas, cotton, eggplant, papayas, peanuts, pigeon peas, potatoes, rice, sorghum, sugarcane, tomatoes, watermelon, and wheat.

Costa Rican researchers are working on drought resistant rice and GM pink pineapple with higher levels of lycopene. The pink pineapple is not yet approved for commercialization.

Several Colombian research institutions have been developing sugarcane varieties resistant to yellow leaf virus and cultivars with increased sugar, biomass and salt, aluminum, and water stress tolerance and GM rice, cassava, cacao, castor bean, sacha inchi, potato, and coffee varieties.

Chile's National Institute of Agricultural Research is developing biotech grapes and tree nuts resistant to fungi and viruses, as well as potatoes, rice, and corn.

Brazil also has several GM crops in the pipeline awaiting commercial approval including potatoes, papaya, rice, and citrus, which are at the early stages of development and approval.

The Bangladesh Agricultural Research Institute and MSU are developing late blight resistant potatoes. Controlled field trials in four research stations commenced in 2023.

Approved GM Events

The ISAAA GM approval database (GMAD) is a one-stop shop that compile biotech events approved for commercialization/planting and importation (food and feed) with a brief description, trait, developer, and year of approval for cultivation and updates online resources for scientists, academics, regulators, media practitioners, and the public (ISAAA,2024).

A total of 614 approvals, with maize having the most approvals (290 events), followed by cotton with 72 events, and potato with 52 events. Many of the events (405 events) have stacked trait events, and 209 events have singular trait events (GMAD, 2024).

Soybeans: In the United States, one of the first and most widespread transgenic crops is the Roundup Ready soybean. These soybeans are engineered to be resistant to glyphosate, the active ingredient in the herbicide Roundup.

Recent Research in Transgenic Crops

Recent research in transgenic crops has focused on several innovative approaches to improve crop performance, sustainability, and food security. They include:

Enhanced Photosynthesis and Chilling Tolerance in Maize: Scientists introduced Rubisco-activating proteins into maize, improving photosynthesis efficiency and tolerance to cold environments. This could lead to higher yields, especially in regions with fluctuating temperatures. These advancements reflect the potential of transgenic crops to meet global challenges related to climate resilience, nutrition, and sustainability, while also sparking debate over biosafety and regulation.

Progress of transgenics development in India

More than 20 crops are under various stages of research and field trials for genetic modification in India, namely Cotton, Rice, Wheat, Maize, Brinjal, Potato, Sorghum, Mustard, Groundnut, Cauliflower, Okra, Chickpea, Pigeon pea, Castor, Sugarcane etc. for the trait's insect resistance, herbicide tolerance, drought tolerance, salinity tolerance, virus resistance, quantitative traits (yield increase), nutrition improvement etc. (Mishra and Shukla 2013; FAO 2014; Gupta and Ahuja, 2016)). Current status of GM crops entered into the GMO regulatory system in India is presented in Table 1. Few events of cotton, brinjal, mustard, maize and chickpea are in final stages of field trials. Bt. Cotton is extensively cultivated commercially in India (Choudhary and Gaur, 2010 and 2015), Cotton was the first commercially successful crop in which cry genes were incorporated to provide resistance against lepidopteron insect pest. After the success of transgenic cotton, cry genes have been incorporated in many crops, *viz.*, potato (Adang *et al.*, 1993), rice (Fujimoto *et al.*, 1993; Wunn *et al.*, 1996), canola (Tabashnik *et al.*, 1993; Stewart *et al.*, 1996; Ramachandran *et al.*, 1998; Halfll *et al.*, 2001), soybean (Parrott *et al.*, 1994; Dufourmantel *et al.*, 2005; Dang and Wei 2007), maize (Koziel *et al.*, 1993; Vaughn *et al.*, 2005), chickpea (Indurker *et al.*, 2007; Acharjee *et al.*, 2010; Mehrotra *et al.*, 2011), alfalfa (Tohidfar *et al.*, 2013), and tomato (Mandaokar *et al.*, 2000; Kumar and Kumar 2004). Apart from cry, other insecticidal genes such as vip genes which encode vegetative insecticidal proteins have been deployed in commercialised crops.

The vip genes were isolated from Bacillus species (B. thuringiensis and B. cereus) (Fang *et al.*, 2007). To date, vip3A(a) and vip3Aa20 genes have been heterologously expressed in cotton and maize, respectively (Table 1 and ISAAA database 2019).

The first transgenic crop approved in India was Bt cotton in 2002. It was genetically modified to resist bollworm, a major pest affecting cotton crops. In India, only Cotton is currently commercially cultivated as a GM crop. Trials are underway for other crops like brinjal, tomato, in addition, India is also considering the commercial release of genetically modified mustard known as Dhara Mustard Hybrid (DMH -11). This GM mustard has genes from a soil bacterium that enhance hybridization, potentially leading to a yield increase of 25-30%. The GEAC approved the environmental release of GM mustard hybrid DMH-11, bringing it closer to full commercial cultivation. However, there is an ongoing legal case in the Supreme Court questioning the permission for transgenic food crops. They seek a stay on GM mustard, citing concerns about farmers using banned herbicides. Previous instances include the GEAC's approval of GM mustard in 2017 with additional tests and the government's indefinite moratorium on GM brinjal in 2010.As of now, this crop has received approval from the GEAC but is yet to receive final clearance from the Ministry of Environment.

Table 1: Status of GM crops entered into the GMO regulatory system in India (Manish Shukla *et al.*,, 2018).

S.	Crop	Trait	Event/*Gene*	Developer	Institutional Type	Status
1.	Cotton	Insect Resistance	MON531/*cry1Ac*	Monsanto	Private	Approved for environmental release
2.	Cotton	Insect Resistance	MON15958/ *cry1Ac*	Monsanto	Private	Approved for environmental release
3.	Cotton	Insect Resistance	Event GFM/*cry1 Ac-cry1Ab*	Nath Seeds	Private	Approved for environmental release
4.	Cotton	Insect Resistance	Event 1/*cry1Ac*	JK Agri Genetics	Private	Approved for environmental release
5.	Cotton	Insect Resistance	BNLA-601/*cry1Ac*	ICAR-CICR, Nagpur, UAS, Dharwad	Public	Approved for environmental release
6.	Cotton	Insect Resistance	MLS-9124/*cry1Ac*	Metahelix	Private	Approved for environmental release
7.	Cotton	Insect Resistance & Herbicide Tolerance	MON15985 x MON88913	Mahyco	Private	Confined field trials for BRL-II
8.	Cotton	Insect Resistance	cry1F gene, *cry1Ac gene*	ICAR-CICR, Nagpur	Public	Event selection trials
9.	Cotton	Insect Resistance	*cry1Ac gene* in *G. arboretum; cry1Ac gene* in *G. barbadense; cry1Ac gene* in *G. herbaceum* cv. Jayadhar; *cry1Ac* and *cry1F genes* in *G. hirsutum*	UAS, Dharwad	Public	Event selection trials
10.	Cotton	Insect Resistance & Herbicide Tolerance	MON 15985 × COT102 (BGIII), MON 15985 x COT102 x MON 88913 (BGIII RRF), COT102	Monsanto	Private	BRL-I trials

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11.	Cotton	Virus Resistance	*cp gene* of TSV	Mahyco	Private	Confined field trials for event selection
12.	Cotton	Herbicide Tolerance	*cp4epsps gene*	Mahyco	Private	Confined field trials
13.	Cotton	Herbicide Tolerance	GHB614/*2m EPSPS*	Bayer Bioscience	Private	BRL-II trials
14.	Cotton	Insect Resistance	Event 281–24-236 & Event 3006–210-23/*cry1F & cry1Ac*	Dow Agroscience	Private	BRL-II trials
15.	Cotton	Water Use Efficiency and Nitrogen Use Efficiency	*ipt* and *AlaAt gene*	Mahyco	Private	Confined field trials for event selection
16.	Cotton	Insect Resistance & Herbicide Tolerance	GHB119 (Cry2Ae/PAT) x T304-40 (Cry1Ab/PAT) x GHB614 (2mEPSPS) x Cot102 (vip3A)	Bayer Bioscience	Private	Confined field trials for BRL-I
17.	Cotton	Herbicide Tolerance	*synthetic EPSPS gene*	Metahelix	Private	Application for event selection trials is under investigation
18.	Cotton	Insect Resistance	*cry1Ac gene*	Metahelix	Private	Application for event selection trials is under investigation
19.	Brinjal	Insect Resistance	EE-1	Mahyco/TNAU /UASD/IIVR	Public-Private	Moratorium
20.	Brinjal	Insect Resistance	Event-142/ *cry1Fa1*	Bejo Sheetal	Private	BRL-II trials
21.	Brinjal	Insect Resistance	cry1Fa1, cry2Aa, stacked cry1Fa1 and cry2Aa	Global Transgenes	Private	Event selection trials
22.	Brinjal	Insect Resistance	ANK-19 event/ Cry1Fa1 gene	Ankur Seeds	Private	BRL-I trials
23.	Brinjal	Insect Resistance	Cry1Fa1 gene	Rasi Seeds	Private	Event selection trials
24.	Mustard	Agronomic Performance	Event bn 3.6 and modbs 2.99/ *barnase, barstar* and *bar genes*	CGMCP, University of Delhi	Public	Recommended by GEAC for environmental release but kept pending for further review
25.	Maize	Insect Resistance	MON89034	Monsanto	Private	BRL-I trials
26.	Maize	Herbicide Tolerance	NK603	Monsanto	Private	BRL-II trials
27.	Maize	Insect Resistance	MON 89034 x NK603	Monsanto	Private	Confined field trials
28.	Maize	Herbicide Tolerance & Insect Resistance	TC1507/*cry1F*, TC1507 (DAS-01507–1)	Dow Agro Sciences	Private	Confined field trials for BRL-I
29.	Maize	Herbicide Tolerance & Insect Resistance	TC1507xNK603	Pioneer Overseas Corporation	Private	BRL-II trials
30.	Maize	Herbicide Tolerance & Insect Resistance	TC15017x MON810xNK603	Pioneer Overseas Corporation	Private	BRL-I trials

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31.	Maize	Insect Resistance & Herbicide Tolerance	Bt11, GA21 and Bt11 x GA21	Syngenta Biosciences	Private	Confined field trials
32.	Maize	Insect Resistance & Herbicide Tolerance	TC1507 x MON 810 x NK 603 (DAS-01570–1 x MON-00810–6 x MON-00603–6) /*cry1F, cry1Ab* and *cp4epsps* genes	Pioneer Hi-Bred	Private	BRL-I trials
33.	Maize	Herbicide Tolerance	cp4epsps	Metahelix	Private	Confined field trials for event selection
34.	Maize	Insect Resistance & Herbicide Tolerance	*cry1F* and *synthetic EPSPS gene*	Metahelix	Private	Application for event selection trials is under investigation
35.	Maize	Insect Resistance & Herbicide Tolerance	*cry1Ab* and *synthetic EPSPS gene*	Metahelix	Private	Application for event selection trials is under investigation
36.	Wheat	Salt Tolerance	*OsNHX1 gene*	Mahyco	Private	Confined field trials for event selection
37.	Wheat	Herbicide tolerance	event MON 71800/*cp4epsps gene*	Mahyco	Private	Confined field trials
38.	Cauliflower	Insect Resistance	Event CFE4	Sungro Seeds	Private	Confined field trials
39.	Okra	Insect Resistance	*cry1Ac gene*	Mahyco, Sungro Seeds	Private	Confined field trials
40.	Potato	Reduced Cold Induced Sweetening	KChipInv RNAi-2214	CPRI, Shimla	Public	BRL-I trials
41.	Potato	Agronomic Performance	*GA20 Oxidase 1gene*	CPRS – CPRI, Jalandhar	Public	Confined field trials for event selection
42.	Potato	Fungal Resistance	*RB gene*	CPRI, Shimla	Public	Event selection trials
43.	Groundnut	Drought Tolerance	*rd29A gene (DREB1A)*	ICRISAT, Hyderabad	Private	Confined field trials for event selection
44.	Rice	Insect Resistance & Herbicide Tolerance	*dual Bt (Cry1Ab & Cry1Ca)* and *bar genes, Cry1Ab & Cry1Ca* and *Cry 2 Ad gene*	Bayer Biosciences	Private	Confined field trials for event selection
45.	Rice	-	-	BASF	Private	Elite event selection trials
46.	Rice	Nutritional Enhancement	*ferritin gene*	Department of Botany, University College of Science, University of Calcutta	Public	Event selection trials
47.	Rice	Salt Tolerant	*OSnhx1 gene*	Mahyco	Private	Event selection trials
48.	Rice	Water use efficiency	*ipt gene*	Mahyco	Private	Event selection trials
49.	Rice	Nitrogen use efficiency	*AlaAt gene*	Mahyco	Private	Event selection trials

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50.	Rice	Insect Resistance	*cry1Ab (DG) gene*	Devgen Seeds & Crop Technology	Private	Event selection trials
51.	Rice	Drought and Salinity tolerance and Nutrition stress	-	Bioseed Research	Private	Confined field trials for elite event selection
52.	Rice	Insect Resistance	*cry2Aa2*	Rasi Seeds	Private	Confined field trials for event selection
53.	Rice	Drought and Salinity tolerance	B6 and C15/*gly I* and *gly II*	Bioseed Research	Private	BRL-I trials
54.	Rice	Drought Tolerance	T I-3 and T I-5/ *DREB*,LEA-11, LEA-20 and LEA-21/*lea*	Bioseed Research	Private	BRL-I trials
55.	Rice	Hybrid Rice SPT Maintainer	*Os-MSCA1*, *Zm-AA1*,*DsRed2*	Pioneer Overseas Corporation	Private	Confined field trials for event selection
56.	Rice	Insect Resistance	Cry1Ab and Cry2Ad genes, Cry1C and Cry1Ab genes	Pioneer Overseas Corporation	Private	Event selection trials
57.	Rice	Insect Resistance	*cry1Ab* and *cry1Ac*, *cry1Ab*	Metahelix	Private	Confined field trials for Event selection
58.	Rice	Insect Resistance	JKOsE081/*cry2 Ax1*JKOsE016/ *cry1Ac*JKOsE081 xE016/*cry2Ax1* and *cry1Ac*	JK Agri Genetics	Private	BRL-I trials
59.	Rice	Herbicide Tolerance	event OS_A17314 /*cp4epsps gene*	Mahyco	Private	BRL-I trials
60.	Golden Rice	Nutritional Enhancement	GR-2	ICAR-IIRR Hyderabad, IARI New Delhi, TNAU Coimbatore	Public	Confined field trials
61.	Chickpea	Insect Resistance	-	AAU Jorhat	Public	Confined field trials
62.	Chickpea	Insect Resistance	SSL-3/*cry1Ac*	Sungro Seeds	Private	Confined field trials
63.	Chickpea	Insect Resistance	SSL-6/*cry2Aa*	Sungro Seeds	Private	BRL-I trials
64.	Chickpea	Insect Resistance	*cry1Ac*/*cry1Aabc*	ICAR-IIPR, Kanpur	Public	Confined field trials for event selection
65.	Pigeonpea	Insect Resistance	*cry1Ac*/*cry1Aabc*	ICAR-IIPR, Kanpur	Public	Confined field trials for event selection
66.	Sorghum	Insect Resistance, Drought and Salinity Tolerance	Event-4/19	ICAR-IIMR, Hyderabad	Public	Confined field trials
67.	Sorghum	Drought Tolerance	-	CRIDA, Hyderabad	Public	Event selection trials
68.	Castor	Insect resistance	*Cry1EC and Cry1Aa genes*	ICAR-IIOR, Hyderabad	Public	Confined field trials for event selection
69.	Sugarcane	Insect Resistance	*cry1Ac gene*	Sugarcane Research Institute, UPCSUR, Shahjahanpur	Public	Confined field trials for event selection

Other transgenic crops which are under developmental phases in India

i. **GE banana:** The National Agri-Food Biotechnology Institute (NABI) in Mohali is developing fungus-resistant varieties and exploring the fortification of bananas with iron. They are also working on increasing the amount of provitamin A in the fruit.

ii. **GE potato:** The Central Potato Research Institute (CPRI) in Shimla has received permission to conduct research on the GE potato hybrid KJ66, derived from the wild Mexican potato, aimed at combating the late blight pathogen Phytophthora infestans.

iii. **GE maize:** Rallis India Limited has received conditional approval from GEAC to conduct trials on GE maize, aimed at improving its resistance to the moth Spodoptera frugiperda and tolerance to the herbicide glyphosate.

iv. **GE rubber:** The Rubber Research Institute in Kottayam has been granted permission for trials of two GE rubber lines expressing an 'osmotin' gene, which is expected to confer resilience to the plants under a range of adverse conditions.

Advantages and Importance of Transgenic Plants

Addressing food security: One of the main arguments supporting the introduction of transgenic crops in India is the potential to enhance food security. With India's population continually growing, transgenic crops offer a promising solution to increase agricultural yield and meet the escalating food demand.

Improved crop characteristics: Transgenic crops can be engineered to have desired traits such as drought resistance, pest resistance, and improved nutritional content. These modifications can lead to healthier, more resilient crops that are better suited to varying climatic conditions and can contribute to higher yields.

Economic benefits for farmers: Transgenic crops can provide economic advantages to farmers. The use of crops genetically engineered to resist pests, for instance, can reduce the need for expensive pesticides. The GEAC's recent approval of GM mustard is a prime example of this, with the potential to boost yield and subsequently increase farmers' income.

Potential environmental benefits: By reducing the need for chemical pesticides and herbicides, transgenic crops may also help decrease environmental pollution. Furthermore, certain GM crops may require less water, contributing to more sustainable water use.

Enhanced crop diversity: Transgenic technology can facilitate the development of new crop varieties, enhancing agricultural biodiversity. This could offer farmers a greater choice of crops to cultivate, potentially leading to more diverse farming systems.

Extended Shelf Life: Delayed ripening crops reduce food spoilage and wastage during transportation and storage.

Environmental Sustainability: Transgenic crops promote sustainable practices by reducing the carbon footprint and conserving soil health. These benefits support global food security, improve farmers' livelihoods, and promote sustainable agricultural practices.

Disadvantages of Transgenic Plants

Health concerns: Some groups argue that the consumption of genetically modified crops could potentially lead to health issues. There are concerns about allergenicity, antibiotic resistance, and the overall safety of consuming foods derived from GMOs.

Impact on biodiversity: Critics also argue that the introduction of transgenic crops could negatively impact biodiversity. There are concerns that the proliferation of GM crops could lead to the genetic contamination of wild relatives of the modified crops. The increased use of herbicide-resistant crops could harm non-target organisms and beneficial insects.

Potential socio-economic implications: There are also socioeconomic considerations. For instance, small farmers might face difficulties if they cannot afford the often higher-priced GM seeds, potentially exacerbating economic inequalities in rural communities.

Dependence on multinational companies: Many GM seeds are patented by multinational corporations. Farmers using these seeds would be dependent on these companies for their supply, potentially leading to monopolistic practices and loss of control over their own agricultural practices. Few corporations control the production of transgenic seeds, limiting farmers' access and increasing dependency.

Ethical and cultural concerns: For some, the genetic modification of crops raises ethical questions about human intervention in nature. These can be especially potent in countries like India with rich cultural and religious traditions tied to natural processes.

Development of Pest Resistance: Over time, target pests may develop resistance to genetically engineered traits, reducing crop effectiveness (ex:., resistance to Bt toxin).

Impact on Non-Target Organisms: Transgenic crops may unintentionally harm beneficial insects, such as pollinators and natural predators.

Environmental Risks: Cross-pollination with non-GMO crops or wild relatives can lead to genetic contamination, affecting biodiversity. Herbicide-tolerant crops may encourage excessive use of herbicides, causing soil degradation and water pollution.

Acts and Rules that Regulate GM Crops in India

1. Environment Protection Act, 1986 (EPA).
2. Biological Diversity Act, 2002.
3. Plant Quarantine Order, 2003.
4. GM policy under Foreign Trade Policy, Food Safety and Standards Act, 2006.
5. Drugs and Cosmetics Rule (8th Amendment), 1988.

Process of Regulating Transgenic Crops in India

1. Developing transgenic crops involves inserting transgenic genes into plants to achieve a sustained, protective response.
2. The process involves a mix of science and chance.
3. Safety assessments by committees are conducted before open field tests.
4. Open field tests are done at agricultural universities or Indian Council for Agricultural Research (ICAR)-controlled plots.
5. Transgenic plants must be better than non-GM variants and environmentally safe for commercial clearance.
6. Open field trials assess suitability across multiple seasons and geographical conditions.

Regulations on genetically modified crops in India

India has a well-established regulatory framework in place to control and supervise the introduction and cultivation of GM crops. This is governed by various rules, regulations, and guidelines set by different ministries and departments.

The Genetic Engineering Appraisal Committee (GEAC) under MoEFCC is authorised to review, monitor and approve all activities including import, export, transport, manufacture, use or sale of GMO.GEAC reviews proposals related to the release of GM organisms and products into the environment, including experimental field trials. In India, the regulation of all activities related to GMOs and products are regulated by the Union Ministry of Environment, Forest and Climate Change (MoEFCC) under the provisions of the Environment (Protection) Act, 1986. The GEAC or people authorised by it have the power to take punitive actions under the Environment Protection Act. GM foods are also subjected to regulations by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006.The ICAR plays a crucial role in supervising the development of new GM varieties and hybrids

Recent Issues with Transgenic Crops at global level

Recent issues surrounding transgenic crops include concerns about environmental, health, and regulatory risks Critics argue that inadequate risk evaluations and transparency could harm biodiversity and human health, while proponents emphasize the crop's potential to boost yields and food security. The broader debate reflects tensions between scientific innovation for agricultural productivity and the precautionary principle, which urges thorough evaluation to prevent potential ecological and health impacts. These discussions highlight the importance of balancing technological progress with public safety and environmental sustainability. In India, the approval of GM mustard (HT Mustard DMH-11) has sparked legal challenges, leading to a split verdict by the Supreme Court, which questioned regulatory procedures and bio-safety assessments. In Canada, gene-edited crops are receiving regulatory support, with authorities framing them as crucial for addressing environmental challenges such as drought and pest resistance. However, questions remain about market access and public trust, especially regarding proper alignment of regulations with international trade partners

Concerns related to Transgenic Crops

The increasing cultivation of transgenic crops has raised several issues with respect to food safety, environmental effects, socio-economic issues and ethical issues. From the food and health perspective, the main concerns are related to possible toxicity and allergenicity of GM foods and products. Concerns about environmental

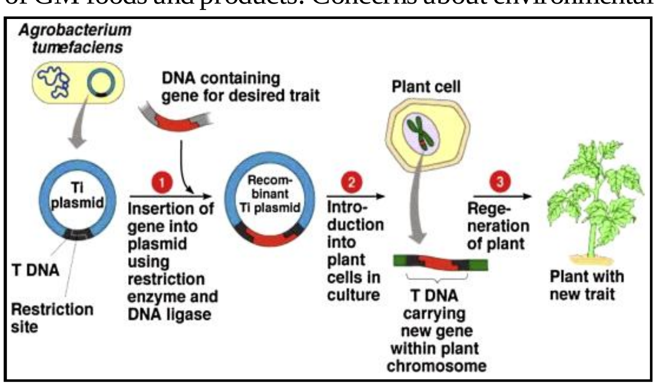

Fig. 1: Method of Transgenic Preparation.

risks of GM crops include the impact of introgression of the transgenes into the natural landscape, impact of gene flow, effect on non-target organisms, evolution of pest resistance and loss of biodiversity**.** A wide gap exists between the rapid acceptance of genetically modified (GM) crops for cultivation by farmers in many countries and in the global markets for food and feed. Transgenic crops are subject of significant debate in India. Despite their potential to combat agricultural challenges, they raise concerns regarding their impact on the environment and human health.

- **a. Lack of Nutritional Value:** GM foods can sometimes lack nutritional value despite their increased production and pest resistance focus. This is because the emphasis is often placed on enhancing certain traits rather than nutritional content.
- **b. Risks to Ecosystems:** GM production can also pose risks to ecosystems and biodiversity. It may disrupt gene flow and harm indigenous varieties, leading to a loss of diversity in the long run.
- **c. Trigger Allergic Reactions:** Genetically modified foods have the potential to trigger allergic reactions since they are biologically altered. This can be problematic for individuals accustomed to conventional varieties (Chen Zhang *et al*., 2016).
- **d. Endangered Animals:** Wildlife is also at risk due to GM crops. For instance, genetically modified plants used for producing plastic or pharmaceuticals can endanger animals like mice or deer that consume crop debris left in fields after harvest.

Way Forward

It involves a multifaceted approach that addresses technological advancements, regulatory frameworks, and public perception.

- **a. Assessment of Risks:** The regulatory framework also requires the evaluation of potential risks to human health, animal health, and biodiversity. This involves rigorous testing under laboratory and field conditions to ensure the safety and efficacy of GM crops. After the introduction, transgenic crops should be continuously monitored to assess their impact on biodiversity and ecosystems. In particular, the potential for gene flow to non-target species should be rigorously evaluated.
- **b. Public Consultation:** In some cases, public consultation is also part of the process before a final decision is made about the commercialization of a GM crop. This allows stakeholders, including the public, to voice their concerns and opinions. Transparent, evidence-based information on GM crops should be shared with the public to address concerns and misconceptions. This could involve engaging with communities through public consultations before the introduction of GM crops
- **c. Enhanced research and development:** To address concerns related to transgenic crops, further research and development should be undertaken. This should focus on comprehensive risk assessment, long-term impact studies, and the development of techniques to prevent cross-contamination. India needs to enhance its capacity in the field of biotechnology. This involves training scientists in advanced techniques and creating world-class laboratories that can undertake cutting-edge research in this field. : India can benefit from international collaboration in this field, learning from the experiences of other countries that have successfully adopted transgenic crops, and working together to address shared challenges. Technology approvals must be streamlined and science-based decisions implemented.
- **d. Rigorous regulatory framework:** The regulatory framework for the approval and monitoring of transgenic crops in India needs to be rigorous. This can help ensure that only those GM crops that are safe for human health and the environment are permitted. The regulatory regime needs to be strengthened, for the sake of domestic as well as export consumers. Streamlining regulatory frameworks can facilitate faster approval for transgenic crops while ensuring safety.
- **e. Protecting farmers' interests:** Policies should be in place to protect farmers from potential exploitation by multinational companies selling GM seeds. This includes ensuring farmers have access to a variety of seeds, including non-GM options. Integrating transgenic crops into sustainable farming practices can enhance their acceptance. This includes demonstrating how these crops can reduce pesticide use, improve soil health, and enhance biodiversity. Increasing awareness and understanding of transgenic crops among consumers, farmers, and policymakers is crucial. Transparent communication about the

benefits, risks, and scientific backing of transgenic crops can help build trust and acceptance.

f. Rigorous monitoring is needed to ensure that safety protocols are followed strictly, and enforcement must be taken seriously to prevent the spread of illegal GM crops. Establishing long-term studies to monitor the environmental impacts and benefits of transgenic crops will provide valuable data to inform policy and public perception. This research should include assessments of biodiversity, soil health, and pest resistance.

g. Focus on Climate Resilience: Continued research into creating transgenic crops that are resilient to climate change, such as drought and temperature extremes, is essential. This aligns with global food security goals and can mitigate the impacts of climate variability on agriculture.

h. Public-Private Partnerships: Collaboration between public institutions and private companies can accelerate research and development in transgenic crops. This synergy can lead to innovative solutions that address local agricultural challenges while sharing risks and benefits.

By focusing on these strategies, stakeholders can foster a more positive and informed dialogue around transgenic crops, ultimately leading to their responsible adoption and utilization in addressing global agricultural challenges.

Conclusions

Transgenic crops are a vital innovation in agricultural biotechnology, addressing challenges such as food security, climate resilience, and pest management. Despite their potential to enhance yields and reduce chemical usage, concerns about biosafety and public acceptance remain. The future of these crops depends on transparent regulations, public education, and ongoing safety research. By promoting collaboration and sustainable practices, transgenic crops can positively impact global agriculture while addressing socio-economic and environmental issues. Continued dialogue and research are essential for fostering a balanced approach to their adoption**.** Achieving a balance between the advantages of transgenics and environmental risks is imperative for ensuring sustainable agriculture and food security.

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